

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: <i>All Wave 5 Cases</i>	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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GENERAL RETAINED EXPERTS

- 1) Dr. Bruce Rosenzweig (Urogynecologist)
Rush University Professional Building
1725 West Harrison Street, Suite 358
Chicago, IL 60612
- 2) Dr. Daniel Elliott (Urologist)
Mayo Clinic
200 1st Street SW
Rochester, MN 55902
- 3) Dr. Jerry Blaivas (Urologist) (adoption of previously served reports)
445 East 77th Street
New York, NY 10075
- 4) Dr. Ralph Zipper (Urogynecologist) (adoption of previously served report)
Zipper Urogynecology
1130 S. Harbor City Boulevard
Melbourne, FL 32901
- 5) Dr. Robert Shull (Urogynecologist) (adoption of previously served report)
Scott & White Clinic & Hospital
Department of Obstetrics and Gynecology
2401 S. 31st Street
Temple, Texas 76508
- 6) Dr. Abbas Shobeiri (Urogyn) (adoption of previously served report)
500 North Washington St
300
Falls Church, VA 22046

- 7) Dr. Vladimir Iakovlev, M.D. (Pathologist) (adoption of previously served report)
St. Michael's Hospital, Division of Pathology
30 Bond Street, Cardinal Carter, Room 2-093
Toronto, ON, M5B1W8
CANADA
- 8) Dr. Paul Michaels (Pathologist) (adoption of previously served report)
Austin, TX
- 9) Prof. Dr. med. Uwe Klinge (Materials) (adoption of previously served report)
KLINIK FÜR ALLGEMEIN-, VISZERAL- UND
TRANSPLANTATIONSCHIRURGIE
RWTH Aachen und Universitätsklinikum Aachen
Pauwelsstraße 30
D-52074 Aachen
Germany
- 10) Prof. Dr.-Ing. Thomas Muehl (Materials) (adoption of previously served report)
FH Aachen - University of Applied Sciences
Labor für Elektrische Messtechnik und Prozessdatenverarbeitung
Eupener Str. 70
52066 Aachen
Germany
- 11) Dr. Howard Jordi (Materials) (adoption of previously served report)
Jordi Labs
200 Gilbert Street
Mansfield, MA 02048
- 12) Dr. Scott Guelcher (Materials)
Polymer and Chemical Technologies, LLC
1008 Caldwell Avenue
Nashville, TN 37204
- 13) Dr. Jimmy Mays (Materials)
Department of Chemistry
University of Tennessee at Knoxville
655 Buehler Hall
Knoxville, TN 37996
- 14) Dr. Russell Dunn (FMEA) (adoption of previously served report)
Polymer and Chemical Technologies, LLC
1008 Caldwell Avenue
Nashville, TN 37204

- 15) Dr. Dionysios Veronikis (Urogyn) (adoption of previously served report)
St. Johns Mercy Medical Center
Tower B
621 S New Ballas Rd
#2002-B
St. Louis, MO 63141
- 16) Dr. Michael Thomas Margolis (Urogyn)
Bay Area Pelvic Surgery
1820 Ogden Dr.
Burlingame, California 94010
- 17) Dr. Anne Wilson (FMEA) (adoption of previously served report)
QA Consulting, Inc.
7500 Rialto Blvd.
Bldg. 1, Ste. 225
Austin, Tx 78735
- 18) Dr. John Miklos (Urogyn) (adoption of previously served report)
3400 Old Milton Parkway
Bldg. C, Suite 330
Alpharetta, GA 30005
- 19) Dr. Neeraj Kohli (Urogyn) (adoption of previously served report)
70 Walnut St
Wellesley, MA 02481
- 20) Dr. Alan Garely (Urogyn) (adoption of previously served report)
1 S Central Ave
Valley Stream, NY 11580
- 21) Dr. Brian Raybon (Urogyn) (adoption of previously served report)
79 Doyle St
Toccoa, GA 30577
- 22) Dr. Robert Moore (Urogyn) (adoption of previously served report)
3400 Old Milton Pkwy
Alpharetta, GA 30005
- 23) Dr. Donald R. Ostergard (Urogyn)
8557 Mountain View Farms Ln
Salida, CO 81201

- 24) Duane Priddy, Ph.D. (Materials) (adoption of previously served report)
Plastic Failure Labs
6004 Camelot Ct
Midland, MI 48640
- 25) Dr. Anne M. Weber (Urogynecologist) (adoption of previously served report)
5626 Sharon Drive
Glen Arm, MD 21057

GENERAL RETAINED REGULATORY EXPERTS

Plaintiffs recognize that the Fourth Circuit has affirmed Judge Goodwin's decision to exclude evidence relating to a manufacturer's compliance with the FDA's 510(k) process. In the event of a contrary ruling, Plaintiffs reserve the right to designate the following General Regulatory Experts:

- 1) Dr. Peggy Pence (Regulatory) Dr. Peggy Pence (Regulatory) (adoption of previously served reports)
Symbion Research International, Inc.
3537 Old Conejo Road, Suite 115
Newbury Park, CA 91320
- 2) Dr. Suzanne Parisian (Regulatory) (adoption of previously served report)
MD Assist, Inc.
7117 N. 3rd Street
Phoenix, AZ 85020

EXHIBIT B

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: <i>All Wave 6 Cases</i>	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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Melbourne, FL 32901
- 5) Dr. Robert Shull (Urogynecologist) (adoption of previously served report)
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- 13) Dr. Jimmy Mays (Materials) (adoption of previously served report)
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Knoxville, TN 37996
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Nashville, TN 37204

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Burlingame, California 94010
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Wellesley, MA 02481
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3400 Old Milton Pkwy
Alpharetta, GA 30005
- 23) Dr. Donald R. Ostergard (Urogyn) (adoption of previously served report)
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Salida, CO 81201

- 24) Duane Priddy, Ph.D. (Materials) (adoption of previously served report)
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- 2) Dr. Suzanne Parisian (Regulatory) (adoption of previously served report)
MD Assist, Inc.
7117 N. 3rd Street
Phoenix, AZ 85020

PROLIFT EXPERT REPORTS	
Blaivas, Jerry	Urologist
Dunn, Russell	FMEA
Elliott, Daniel	Urologist
Garely, Alan	Urogyn
Guelcher, Scott	Materials
Iakovlev, Vlad	Pathologist
Jordi, Howard	Materials
Klinge, Uwe	Materials
Mays, Jimmy	Materials
Michaels, Paul	Pathologist
Muehl, Thomas	Materials
Ostergard, Donald	Urogyn
Pence, Peggy	Regulatory
Priddy, Duane	Materials
Raybon, Brian	Urogyn
Shoberi, Abbas	Urogyn
Shull, Robert	Urogyn
Weber, Anne	Urogyn
Zipper, Ralph	Ob/GYN
PROLIFT+M EXPERT REPORTS	
Dunn, Russell	FMEA
Garely, Alan	Urogyn
Guelcher, Scott	Materials
Iakovlev, Vlad	Pathologist
Mays, Jimmy	Materials
Muehl, Thomas	Materials
Parisian, Suzanne	Regulatory
Priddy, Duane	Materials
Raybon, Brian	Urogyn
Shull, Robert	Urogyn
PROSIMA EXPERT REPORTS	
Dunn, Russell	FMEA
Guelcher, Scott	Materials
Jordi, Howard	Materials
Klinge, Uwe	Materials
Mays, Jimmy	Materials
Michaels, Paul	Pathologist
Muehl, Thomas	Materials
Pence, Peggy	Regulatory
Priddy, Duane	Materials
Rosenzweig, Bruce	Urogyn
Shull, Robert	Urogyn
Zipper, Ralph	Ob/GYN

TVT RETROPUBIC EXPERT REPORTS	
Blaivas, Jerry	Urologist
Elliott, Daniel	Urologist
Guelcher, Scott	Materials
Iakovlev, Vlad	Pathologist
Jordi, Howard	Materials
Klinge, Uwe	Materials
Margolis, Thomas	Urogyn
Mays, Jimmy	Materials
Michaels, Paul	Pathologist
Muehl, Thomas	Materials
Pence, Peggy	Regulatory
Priddy, Duane	Materials
Rosenzweig, Bruce	Urogyn
Veronikis, Dionysios	Urogyn
Wilson, Anne	FMEA
TVT-O EXPERT REPORTS	
Blaivas, Jerry	Urologist
Elliott, Daniel	Urologist
Guelcher, Scott	Materials
Iakovlev, Vlad	Pathologist
Jordi, Howard	Materials
Klinge, Uwe	Materials
Kohli, Neeraj	Urogyn
Margolis, Thomas	Urogyn
Mays, Jimmy	Materials
Michaels, Paul	Pathologist
Moore, Robert	Urogyn
Muehl, Thomas	Materials
Pence, Peggy	Regulatory
Priddy, Duane	Materials
Rosenzweig, Bruce	Urogyn
Shoberi, Abbas	Urogyn
Wilson, Anne	FMEA
TVT-S EXPERT REPORTS	
Blaivas, Jerry	Urologist
Elliott, Daniel	Urologist
Guelcher, Scott	Materials
Iakovlev, Vlad	Pathologist
Jordi, Howard	Materials
Klinge, Uwe	Pathologist
Mays, Jimmy	Materials
Michaels, Paul	Pathologist
Miklos, John	Urogyn
Muehl, Thomas	Materials

Parisian, Suzanne	Regulatory
Priddy, Duane	Materials
Rosenzweig, Bruce	Urogyn
Wilson, Anne	FMEA
Zipper, Ralph	Ob/GYN
TVT ABBREVO EXPERT REPORTS	
Blaivas, Jerry	Urologist
Guelcher, Scott	Materials
Iakovlev, Vlad	Pathologist
Klinge, Uwe	Materials
Mays, Jimmy	Materials
Michaels, Paul	Pathologist
Muehl, Thomas	Materials
Priddy, Duane	Materials
Rosenzweig, Bruce	Urogyn
TVT EXACT EXPERT REPORTS	
Blaivas, Jerry	Urologist
Guelcher, Scott	Materials
Iakovlev, Vlad	Pathologist
Klinge, Uwe	Materials
Mays, Jimmy	Materials
Muehl, Thomas	Materials
Michaels, Paul	Pathologist
Priddy, Duane	Materials
Rosenzweig, Bruce	Urogyn
GYNEMESH/GYNEMESH PS FLAT MESH	
Guelcher, Scott	Materials
Iakovlev, Vlad	Pathologist
Klinge, Uwe	Materials
Mays, Jimmy	Materials
Michaels, Paul	Pathologist
Muehl, Thomas	Materials

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION <hr/> THIS DOCUMENT RELATES TO: <i>ALL WAVE 6 CASES</i>	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**CERTIFICATE OF SERVICE OF PLAINTIFF'S DESIGNATION AND DISCLOSURE
OF GENERAL EXPERT WITNESSES**

I hereby certify that on July 27, 2017, I electronically served Plaintiff's Designation and Disclosure of General Expert Witnesses on counsel of record listed below.

Christy D. Jones
christy.jones@butlersnow.com
William Gage
william.gage@butlersnow.com
Butler, Snow, O'Mara, Stevens & Cannada, PLLC
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010

David B. Thomas
dthomas@tcspllc.com
Thomas, Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824

/s/ Bryan F. Aylstock

Bryan F. Aylstock

D. Renee Baggett

Aylstock, Witkin, Kreis and Overholtz, PLC

17 E. Main Street, Suite 200

Pensacola, FL 32502

850-202-1010

850-916-7449

baylstock@awkolaw.com

Counsel For Plaintiff

EXHIBIT C

From: Timothy Jackson
To: [David Thomas](#)
Cc: [Aaron Arthur](#); [Robyn Davis](#); [Edward Wallace](#)
Subject: RE: Guelcher
Date: Wednesday, August 16, 2017 2:31:04 PM
Attachments: [Supplemental TVM JBS Poly Ed.pdf](#)

David:

The supplemental data for the 2017 study is attached.

Tim

From: David Thomas [<mailto:DThomas@tcspllc.com>]
Sent: Wednesday, August 16, 2017 8:22 AM
To: Timothy Jackson
Cc: Aaron Arthur; Robyn Davis; Edward Wallace; David Thomas
Subject: RE: Guelcher

I am sure it was just oversight, but the supplemental data referenced in the study is not attached to the 2017 study. We also asked for all of the raw data (FTIR, XPS, etc.) underlying the 2017 study. If you are refusing to produce, we will deal with at a later time. But if you are willing to produce, please make sure that is included in the production. Thank you.

David

From: Timothy Jackson [<mailto:TEJ@wexlerwallace.com>]
Sent: Tuesday, August 15, 2017 6:31 PM
To: David Thomas <DThomas@tcspllc.com>
Cc: Aaron Arthur <AArthur@tcspllc.com>; Robyn Davis <RDavis@tcspllc.com>; Edward Wallace <EAW@wexlerwallace.com>
Subject: RE: Guelcher

David:

We sent you a final copy of Dr. Guelcher's 2017 article earlier today. Without waiving any of our objections, the other materials have already been produced at prior depositions. We will get you billing information.

Thanks,
Tim

From: Edward Wallace
Sent: Tuesday, August 15, 2017 4:00 PM
To: David Thomas
Cc: Aaron Arthur; Robyn Davis; Timothy Jackson
Subject: RE: Guelcher

Just so we don't run into issues – we are giving you docs tomorrow but some seem duplicative. Keep Tim on this chain and pls raise issues you have, if any, w production so we only do this once. I know you like that idea too – so thanks.

From: David Thomas [<mailto:DThomas@tcspllc.com>]
Sent: Sunday, August 13, 2017 8:50 PM
To: Edward Wallace <EAW@wexlerwallace.com>
Cc: Aaron Arthur <AArthur@tcspllc.com>; Robyn Davis <RDavis@tcspllc.com>
Subject: RE: Guelcher

I will make the 17th work provided you do not complain of inadequate time to produce the documents we request for the deposition. They should be readily accessible. We will schedule the deposition for 9 a.m. at Butler Snow in Nashville. Notice will be filed tomorrow. I have some medical tests tomorrow so will be hard to catch. Email best. Please confirm. David

From: David Thomas
Sent: Sunday, August 13, 2017 9:46 PM
To: Edward Wallace <EAW@wexlerwallace.com>
Cc: Aaron Arthur <AArthur@tcspllc.com>; Robyn Davis <RDavis@tcspllc.com>
Subject: RE: Guelcher

From: Edward Wallace [<mailto:EAW@wexlerwallace.com>]
Sent: Sunday, August 13, 2017 9:18 PM
To: David Thomas <DThomas@tcspllc.com>
Cc: Aaron Arthur <AArthur@tcspllc.com>
Subject: Re: Guelcher

The problem is that this ruling comes around his family vacation, commitments he cannot move and a work trip overseas. I have finally nailed down the morning of August 17, which is this Thursday. He says that is literally the only date that he can do given the time constraints and he is delaying a trip just to make himself available. I assume you don't have much at all in the way of questions and he needs to be done by noon that day. Otherwise, it looks like he would have to be deposed by video from overseas if that and would likely then be available in the US after Labor Day. Let me know tonight or first thing in the a.m. as possible.

On Aug 13, 2017, at 10:03 AM, David Thomas <DThomas@tcspllc.com> wrote:

I am available the entire week of August 21. Out this week in meetings and the week of Labor Day in depositions.

On Aug 13, 2017, at 10:52 AM, Edward Wallace <EAW@wexlerwallace.com> wrote:

David – will you be overseas at all? I believe Dr. Guelcher is headed that

way shortly and work commitments before then are making this problematic. Can you give me a sense of your schedule so we can do what we can here?

From: David Thomas [<mailto:DThomas@tcspllc.com>]

Sent: Friday, August 11, 2017 2:46 PM

To: Edward Wallace <EAW@wexlerwallace.com>

Cc: Aaron Arthur <AArthur@tcspllc.com>

Subject: Guelcher

Ed—following up on dates. Thanks.

David

David B. Thomas

Thomas, Combs & Spann PLLC
300 Summers Street, Suite 1380
Charleston, WV 25301

Telephone (main)—304-414-1800
Telephone (direct)—304-414-1807

EXHIBIT D

Scott A. Guelcher, Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC
REPAIR SYSTEM PRODUCTS LIABILITY
LITIGATION,

Plaintiff,

v.

THIS DOCUMENT RELATES TO CASE:
WAVE 5 CASES,

Defendant.

MASTER FILE 2:12-MD-02327
MDL 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

DEPOSITION OF SCOTT A. GUELCHER, PH.D.

AUGUST 17, 2017

- - -

Deposition of SCOTT A. GUELCHER, PH.D. held at
Butler Snow, LLP, 150 3rd Avenue South, Suite 1600,
Nashville, Tennessee, commencing at 8:30 a.m., on the above
date, before Gina Hawkins, Tennessee Licensed Court
Reporter.

Scott A. Guelcher, Ph.D.

Page 2	Page 4
<p>1 INDEX</p> <p>2 WITNESS PAGE</p> <p>3 SCOTT A. GUELCHER, PH.D.</p> <p>4 Examination by Mr. Thomas 4</p> <p>5</p> <p>6 EXHIBITS</p> <p>7 Number</p> <p>8 1 Article entitled "Oxidation and 4</p> <p>9 degradation of polypropylene transvaginal</p> <p>10 mesh"</p> <p>11 2 Document entitled "Supplemental Data, 5</p> <p>12 Supplemental Materials and Methods"</p> <p>13 3 Expert Report of Scott Guelcher, Ph.D. 52</p> <p>14 4 Published Conference Proceedings 68</p> <p>15 5 Second Amended Notice of Deposition 86</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 SCOTT A. GUELCHER, PH.D.</p> <p>2 after having been first duly sworn, was examined and</p> <p>3 testified as follows:</p> <p>4 EXAMINATION</p> <p>5 BY MR. THOMAS:</p> <p>6 Q Good morning, Dr. Guelcher.</p> <p>7 A Good morning.</p> <p>8 (Exhibit 1 was marked for identification.)</p> <p>9 BY MR. THOMAS:</p> <p>10 Q Dr. Guelcher, I'm going to hand you Deposition</p> <p>11 Exhibit Number 1. This is a paper from the Journal of</p> <p>12 Biomaterials Science, Polymer Edition, 2017 titled</p> <p>13 "Oxidation and degradation of polypropylene transvaginal</p> <p>14 mesh."</p> <p>15 You're familiar with that document, aren't you?</p> <p>16 A Yes.</p> <p>17 Q You're one of the authors on this paper?</p> <p>18 A Yes.</p> <p>19 Q And in fact, you're the corresponding author?</p> <p>20 A Yes.</p> <p>21 Q What does it mean to be a corresponding author?</p> <p>22 A That means that I handle all the correspondence</p> <p>23 with the editor, editorial office.</p> <p>24 Q And do you handle any questions that people might</p> <p>25 have about the content of the study for readers?</p>
Page 3	Page 5
<p>1 APPEARANCES</p> <p>2 (Appearing on behalf of the Plaintiff)</p> <p>3 TIMOTHY E. JACKSON, ESQUIRE</p> <p>4 Wexler Wallace, LLP</p> <p>5 55 West Monroe Street</p> <p>6 Suite 3300</p> <p>7 Chicago, Illinois 60603</p> <p>8 tej@wexlerwallce.com</p> <p>9</p> <p>10 (Appearing on behalf of the Defendant)</p> <p>11</p> <p>12 DAVID B. THOMAS, ESQUIRE</p> <p>13 Thomas, Combs & Spann, PLLC</p> <p>14 300 Summers Street</p> <p>15 Charleston, West Virginia 25301</p> <p>16 dthomas@tcspllc.co</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 A Well, yeah, all the authors together respond to</p> <p>2 comments from reviewers, and then I send the final response</p> <p>3 to the journal.</p> <p>4 Q Okay. You're the point person for any issues</p> <p>5 that might arise around the article?</p> <p>6 A That's right.</p> <p>7 (Exhibit 2 was marked for identification.)</p> <p>8 BY MR. THOMAS:</p> <p>9 Q Let me show you Deposition Exhibit Number 2. And</p> <p>10 Deposition Exhibit Number 2 is titled "Supplemental Data,</p> <p>11 Supplemental Materials and Methods."</p> <p>12 Do you recognize this document?</p> <p>13 A Yes.</p> <p>14 Q And is this the supplemental data that's</p> <p>15 referenced on the first page of Exhibit Number 1 down at the</p> <p>16 bottom?</p> <p>17 A Yes, I believe so.</p> <p>18 Q And this is the data -- Exhibit Number 2 is the</p> <p>19 data that Exhibit Number 1 refers to for the tables and</p> <p>20 figures contained in that Exhibit Number 1; is that correct?</p> <p>21 A Yeah. There's a citation to the supplemental</p> <p>22 data in the paper.</p> <p>23 Q Was the supplemental data made available at the</p> <p>24 same time as the original study?</p> <p>25 A What do you mean by "made available"?</p>

2 (Pages 2 to 5)

Scott A. Guelcher, Ph.D.

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<p>1 Q At the time that you published Exhibit Number 1, 2 was Exhibit Number available? 3 MR. JACKSON: Objection to form. 4 A I didn't check that, but that's usually the 5 standard practice in the papers published. It's typically 6 published with the supplemental data at the time. 7 BY MR. THOMAS: 8 Q That was -- I'm sorry. I didn't mean to 9 interrupt you. 10 That was your intent at the time to have the 11 Exhibit Number 1 and Exhibit No. Number 2 available to the 12 reader at the same time? 13 A Yeah, but that's the editorial office. I mean, 14 you know, I submit the documents to the editor at the same 15 time, and then the Journal makes it available online. So I 16 can't control that. 17 That's the way it's typically done, but what I 18 control is what I submit to the editorial office. 19 Q Okay. Who is Anne Talley? 20 A She was my former graduate student. 21 Q And what contribution did Anne Talley make to 22 this Exhibit Number 1? 23 A I believe that she -- let's see if I addressed 24 that in the paper. I don't remember if I did or not. 25 Q I don't believe that you did, but take your time.</p>	<p>1 A He assisted with writing the manuscript. 2 Q I'll note that Dr. Dunn, Russell Dunn, who's also 3 an author, his company is noted as a sponsor of the study. 4 What other contribution did Russell Dunn have in 5 Exhibits 1 and 2? 6 MR. JACKSON: Object to form of the last 7 question. 8 A So Dr. Dunn, his company, as you said, funded the 9 study. He performed the experiments. I should be more 10 specific. 11 The FTIR and the SEM measurements were performed 12 by Dr. Dunn and people that were being supported by the 13 grant, I believe. He would know more of the details, but I 14 would say that he did the FTIR and SEM experiments. 15 BY MR. THOMAS: 16 Q And what contribution did you have to Exhibit 17 Number 1? 18 A So I wrote the first draft of the paper. I 19 compiled all the data from my collaborators, my student. I 20 prepared some of the figures, I think, and I did most of the 21 writing. 22 Q Who owns the FTIR equipment that was used in the 23 study? 24 A I don't -- I don't know. Russell Dunn would know 25 the details of that. I don't know who owns that equipment.</p>
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<p>1 A Yeah, so Anne, I think, did the analysis of the 2 FTIR data to calculate the peak areas. I believe she did 3 some of that work. 4 It's hard to remember exactly what else. She 5 contributed to the writing, probably some of the methods, 6 but it's hard to say, you know, exactly who wrote what. I 7 would say she contributed to writing and analysis of the 8 FTIR data. 9 Q And what is her area of expertise? 10 A Well, biomaterials. She works for FDA now, so 11 has expertise in biomaterials. 12 Q And who is Bridget Rogers? 13 A So Bridget Rogers is an associate professor in my 14 Department of Chemical Engineering at Vanderbilt. 15 Q And what contribution did Ms. Rogers make to this 16 Exhibit Number 1? 17 A So her area of expertise is in films, XPS. So 18 her contribution was, she did the XPS experiments, she 19 analyzed the data. She largely wrote a lot of the parts of 20 the paper on XPS. That's her area of expertise. 21 Q And in the report I note that Dr. Iakovlev, who's 22 also an author, contributed the AMS explant and also cleaned 23 the AMS explant. 24 Did Dr. Iakovlev make any other contribution to 25 Exhibits 1 or 2?</p>	<p>1 Q Same answer for the scanning electron microscope 2 and XPS? 3 A No. The SEM is a Vanderbilt resource, and so is 4 the XPS. 5 Q Who was the person responsible for discussing 6 with Vanderbilt the use of the XPS and SEM equipment for 7 purposes of Exhibit Number 1 and 2? 8 A Well, that would be Dr. Dunn. 9 Q Did you have any involvement in that? 10 A Any involvement in what specifically? 11 Q In any negotiations or discussions with 12 Vanderbilt about the use of the XPS and SEM for the work 13 that's reflected in Exhibits 1 and 2. 14 A No, I don't believe so. That was Dr. Dunn's 15 responsibility. 16 Q Did you have any control over the disbursement of 17 funds that were provided by Russell Dunn's group for this 18 study? 19 MR. JACKSON: Objection to form. 20 A No, I didn't. 21 BY MR. THOMAS: 22 Q Do you know whether Vanderbilt was compensated 23 for the use of their XPS and SEM equipment? 24 A So the SEM is a core resource at Vanderbilt. 25 What that means is, you pay a user fee to use it. And when</p>

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<p style="text-align: right;">Page 10</p> <p>1 it says -- so in the acknowledgments we say that this work</p> <p>2 was supported by Polymer Chemical Technologies. Polymer</p> <p>3 Chemical Technologies paid the user fee for that SEM.</p> <p>4 I don't remember how the XPS was handled. For</p> <p>5 the SEM it's a core resource, so the University was paid</p> <p>6 through that billing agreement.</p> <p>7 Q What do you mean by "core resource"?</p> <p>8 A So large pieces of equipment like SEM are -- it's</p> <p>9 not possible for individual professors to own things like</p> <p>10 this because they're so expensive to maintain, but many</p> <p>11 people want to use it. So we have large equipment like SEM</p> <p>12 that isn't a core. In this case it's the Institute for</p> <p>13 Nanoscale -- Nanoscience and Engineering. And in order to</p> <p>14 recover the costs of using the equipment, that core charges</p> <p>15 an hourly rate, and then that rate has to be paid. In this</p> <p>16 case it was paid by PCT.</p> <p>17 So it's a facility that's owned by the</p> <p>18 University, and anybody can access it by paying the user</p> <p>19 fee. It's an hourly fee.</p> <p>20 Q And did I understand you to say you do not know</p> <p>21 how the University was compensated for use of XPS equipment?</p> <p>22 A I do not. That would be -- so the XPS is owned</p> <p>23 by the University. Dr. Rogers is the one who coordinates</p> <p>24 the use of the XPS.</p> <p>25 There have been some changes to how that is</p>	<p style="text-align: right;">Page 12</p> <p>1 that polypropylene would oxidize under stimulated in-vivo</p> <p>2 conditions.</p> <p>3 Q What does this study tell us about any oxidation</p> <p>4 under in-vivo conditions?</p> <p>5 A Well, we used a test solution. I believe that's</p> <p>6 addressed on page 3, the last paragraph in the introduction.</p> <p>7 We used an oxidized media that comprised 20 percent hydrogen</p> <p>8 peroxide and the cobalt chloride, which causes this reaction</p> <p>9 to form hydroxyl radicals, which are a form of reactive</p> <p>10 oxygen species that's present in-vivo, so we were simulating</p> <p>11 that -- those oxidative conditions.</p> <p>12 That paper has been known for some time and cited</p> <p>13 a number of times. So that was the -- that was the</p> <p>14 approach.</p> <p>15 Q You also it tested an AMS explant; correct?</p> <p>16 A That's right.</p> <p>17 Q And for what purpose did you test the AMS</p> <p>18 explant?</p> <p>19 A I hope it's okay, what I'd like to do is read --</p> <p>20 discuss right from the paper what I said because it's been a</p> <p>21 while. I don't -- I'm just taking a little time, if that's</p> <p>22 okay.</p> <p>23 Q Sure. Let me ask you this question: Did you</p> <p>24 review Exhibits 1 and 2 prior to your deposition?</p> <p>25 A I did, but I didn't have a lot of time. This</p>
<p style="text-align: right;">Page 11</p> <p>1 managed, and I just don't remember what was in place at that</p> <p>2 time.</p> <p>3 Q At the time that you used the University's</p> <p>4 equipment, are you required to disclose the purpose for</p> <p>5 which you're using it?</p> <p>6 A No. It's -- you just pay the user's fee. I</p> <p>7 mean, you would have to disclose it if it's potentially --</p> <p>8 you know, if it's a concern about safety, but this is a</p> <p>9 pretty standard analysis. So typically that's not done.</p> <p>10 Q Did you -- did you or any of the other authors,</p> <p>11 to your knowledge, disclose to the University that you were</p> <p>12 using their XPS and SEM machines for this specific study?</p> <p>13 A No, there would be no reason for that.</p> <p>14 Q Okay.</p> <p>15 A That was handled through the -- Dr. Dunn had</p> <p>16 his -- PCT had a contractual relationship with the</p> <p>17 University, and so once that relationship is established,</p> <p>18 you're free to use the resources like you would for</p> <p>19 another --</p> <p>20 Q Doctor, what was the purpose of Exhibit Number 1?</p> <p>21 What were you trying to set out to do?</p> <p>22 A I believe we addressed that in the abstract. So</p> <p>23 in the study we hypothesized that polypropylene oxidizes</p> <p>24 under in-vitro conditions simulating the foreign body</p> <p>25 reaction so that the purpose was to test that hypothesis</p>	<p style="text-align: right;">Page 13</p> <p>1 just came about pretty fast, and I published this awhile</p> <p>2 ago.</p> <p>3 So I've reviewed these documents. I just want to</p> <p>4 be careful. So I believe that you asked me what's the</p> <p>5 purpose of the -- why did we test the explanted fiber?</p> <p>6 That's what you asked?</p> <p>7 Q That's right.</p> <p>8 A I can't find what I'm looking for right now, but</p> <p>9 basically we were testing the hypothesis that this oxidation</p> <p>10 could also happen in-vivo. That was the question we were</p> <p>11 asking is, can fiber also be oxidized in-vivo in the body.</p> <p>12 Q And you obtained this AMX -- sorry.</p> <p>13 Doctor, you obtained this AMS implant from Dr.</p> <p>14 Iakovlev?</p> <p>15 A That's right.</p> <p>16 Q Do you know what kind of implant it was?</p> <p>17 A We had some discussion about this. I can tell</p> <p>18 you if it's in the -- because of patient confidentiality, we</p> <p>19 were limited in what we knew, but I can tell you what we did</p> <p>20 know.</p> <p>21 So all we know is that it was an AMS midurethral</p> <p>22 sling. We don't know the product. We just know that it was</p> <p>23 a sling.</p> <p>24 Q Do you know how long it was in the patient?</p> <p>25 A We do not.</p>

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<p style="text-align: right;">Page 14</p> <p>1 Q Do you know the reasons the midurethral sling was 2 removed?</p> <p>3 A Well, it was explanted for complications other 4 than mucosal erosion. This is what we know from the 5 records.</p> <p>6 Q Is that all that you know?</p> <p>7 A Yeah. We put in the paper what we knew about the 8 explant.</p> <p>9 Q I'm sorry if I asked this already. My head is a 10 little fuzzy, too.</p> <p>11 Doctor, do you know how long the AMS implant was 12 in the patient before it was removed?</p> <p>13 A Yeah, I said unfortunately we don't. This is all 14 we could get from the patient records is that it was 15 explanted for some complication other than erosion.</p> <p>16 Q Doctor -- sorry. You finished?</p> <p>17 A Yes.</p> <p>18 Q Doctor, the paper reports that Dr. Iakovlev 19 cleaned this AMS explant; correct?</p> <p>20 A That's right. He did that work.</p> <p>21 Q Did he do that at his laboratory in Toronto?</p> <p>22 A He did.</p> <p>23 Q Did he record his methodology in removing the 24 tissue, as he's explained in the report?</p> <p>25 A So we explained -- he does a microscopic</p>	<p style="text-align: right;">Page 16</p> <p>1 Rogers performed the XPS. Dr. Dunn did the FTIR and SEM. 2 So they would have that experimental data. I don't have it. 3 I didn't do the work.</p> <p>4 Q Have you reviewed any of the experimental data, 5 written experimental data upon which Drs. Dunn, Iakovlev, 6 Talley and Rogers relied to generate the data that's in 7 Exhibits 1 and 2?</p> <p>8 A Yeah, I've reviewed the raw data with them as we 9 were writing the paper, but I don't have it. I mean, as we 10 were preparing the figures and writing the manuscript, I 11 reviewed the data with them.</p> <p>12 Q Did you have it in electronic form or hard copy?</p> <p>13 A I don't remember. I think -- I don't remember. 14 Usually what I do with my students is, I get the figures, 15 and then in some cases I'll put the figures together into 16 panels, but I don't -- we don't -- I don't necessarily keep 17 the raw data on the studies on my computer. We store that 18 elsewhere. I mean, I don't --</p> <p>19 Q Where did you store the raw data that was used to 20 generate Exhibits Number 1 and 2?</p> <p>21 A Again, that would be Dr. Dunn's data. I didn't 22 do it.</p> <p>23 Q Dr. Guelcher, I'm not trying to be difficult. 24 You testified that you reviewed the raw data generated by 25 these folks as you did their work with them.</p>
<p style="text-align: right;">Page 15</p> <p>1 dissection where he can remove pieces of tissue using some 2 small tweezers under a microscope, and a scalpel blade he 3 used as well.</p> <p>4 So he developed this technique, and I believe 5 he's been using it for some time.</p> <p>6 Q Have you seen a written protocol for the cleaning 7 of the mesh that's described in Exhibits 1 and 2?</p> <p>8 A I don't remember. I don't know that I've seen a 9 written protocol. I mean, the level of detail that we 10 provided in the paper is consistent with what, you know, you 11 typically would do in a paper.</p> <p>12 I haven't seen -- I don't know if he has a 13 detailed protocol. I just know that he's done this for some 14 time.</p> <p>15 Q Do you know whether he has any notes or records 16 of the procedure he followed to clean the AMS explant?</p> <p>17 A I don't know the answer to that either.</p> <p>18 Q Do you know if he has any photographs that he 19 took during the cleaning procedure?</p> <p>20 A Again, I suspect that he does, but I haven't seen 21 them. He would be able to provide that information.</p> <p>22 Q As a part of this study, was it your practice to 23 keep laboratory notebooks of the work that you performed?</p> <p>24 A Again, Dr. Dunn did all of that. So, again, just 25 to make it clear, Dr. Iakovlev prepared the fibers. Dr.</p>	<p style="text-align: right;">Page 17</p> <p>1 A Yeah.</p> <p>2 Q At some point you had access to that data. What 3 did you do with the data that you reviewed with your 4 co-authors as they generated the data that goes into 5 Exhibits 1 and 2?</p> <p>6 MR. JACKSON: I think that's asked and answered 7 at this point.</p> <p>8 A I don't remember the details. This was awhile 9 ago. But, for example, you would run an FTIR spectrum on 10 the FTIR machine, and those data would be stored in that 11 computer, and then we would pull them up and look at the 12 data.</p> <p>13 And then the final disposition of those data, I 14 don't know if Dr. Dunn left it on that computer or moved it 15 off and stored it somewhere else. I don't know. It's not 16 my data.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q Is it fair to understand that as you sit here 19 today, you don't have access to any of the raw data 20 underlying Exhibits Number 1 and 2?</p> <p>21 A What do you mean by "access"?</p> <p>22 Q Could you get it if you wanted it?</p> <p>23 A Yeah. I would go to Dr. Dunn and get the data.</p> <p>24 Q And you would expect Dr. Dunn to have all of the 25 data that underlies Exhibits Number 1 and 2?</p>

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<p>1 A That would be my -- I mean, when you do</p> <p>2 collaborative scientific research projects like this, each</p> <p>3 investigator controls his or her -- it's just the way -- the</p> <p>4 collegial way to do it. Each investigator controls his or</p> <p>5 her raw data, is responsible for storing that under some</p> <p>6 kind of long-term conditions, but we do so many runs on the</p> <p>7 instrument, it's not typical to leave all the data there.</p> <p>8 At some point somebody takes it off and stores it somewhere,</p> <p>9 but I don't typically do that.</p> <p>10 Q I understand. I'm just trying to figure out</p> <p>11 where it might be.</p> <p>12 A Well, Dr. Dunn would have it. I mean --</p> <p>13 Q Would he have -- are you finished?</p> <p>14 A Yeah.</p> <p>15 Q Would Dr. Dunn, as far as you're concerned as the</p> <p>16 corresponding author, have control of the data from Talley,</p> <p>17 Rogers, Iakovlev and Dunn?</p> <p>18 A I want to be really clear because I feel like</p> <p>19 there's some confusion. I may take a little bit of time to</p> <p>20 answer.</p> <p>21 Q Sure.</p> <p>22 A So just to make it clear, Dr. Dunn did the FTIR</p> <p>23 and the SEM, or people that worked for Dr. Dunn. I don't</p> <p>24 know the details of his arrangement. He's the PI for that</p> <p>25 part of the work, principal investigator for that part of</p>	<p>1 way -- this was a research project. I want to make it</p> <p>2 really clear. This was not testing for litigation. This</p> <p>3 was a research project.</p> <p>4 Q Doctor, is it fair to understand you didn't ask</p> <p>5 Dr. Dunn or any of the other co-authors for their data in</p> <p>6 order to prepare for this deposition?</p> <p>7 A I did not because I didn't think it was</p> <p>8 appropriate.</p> <p>9 Q All right. Let's go to Exhibit Number 1, please,</p> <p>10 and go to page 7.</p> <p>11 By the way, in preparation for your deposition,</p> <p>12 have you read the expert reports of Dr. Thames and</p> <p>13 Dr. McLean?</p> <p>14 A I've read them in the past several months. I</p> <p>15 didn't have time to go through them again last night, but I</p> <p>16 have read them in the past several months, I'd say.</p> <p>17 Q Have you read their criticisms of this -- what</p> <p>18 I'll call the Talley paper?</p> <p>19 A I have, but I don't remember exactly what those</p> <p>20 were.</p> <p>21 Q When you read the criticisms of the Talley paper,</p> <p>22 did you go back to investigate those criticisms?</p> <p>23 MR. JACKSON: Objection, form.</p> <p>24 A Investigate? I don't remember. I mean, I don't</p> <p>25 know how appropriate it is to talk about other litigation</p>
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<p>1 the work. For the FTIR and the SEM, he would have those raw</p> <p>2 data.</p> <p>3 Now, my student didn't do those measurements.</p> <p>4 She did the analysis. But again, everything was given</p> <p>5 back -- Dr. Dunn would have all of that. The XPS was done</p> <p>6 by Dr. Rogers, so she would have -- any additional data on</p> <p>7 the XPS Dr. Rogers would have.</p> <p>8 And then the only thing that Dr. Iakovlev would</p> <p>9 have would be protocols and pictures, et cetera, of how he</p> <p>10 prepared the fibers. He would have that.</p> <p>11 So if you wanted all that, you'd have to go to</p> <p>12 them to get it because it's their work. It's not my work.</p> <p>13 I worked with them to write the paper. I concede to the</p> <p>14 hypothesis and took the lead on writing the paper, but I</p> <p>15 relied on my colleagues to provide the raw data. So that's</p> <p>16 why I don't have it.</p> <p>17 It is -- I don't want to give the impression that</p> <p>18 it's not accessible. It's just under the control of my</p> <p>19 colleagues who prepared it.</p> <p>20 Q But to be clear, if you wanted access to the</p> <p>21 data, you could request it of them, and they would give it</p> <p>22 to you?</p> <p>23 A I'm not comfortable doing that because it's not</p> <p>24 my work, and it's a legal proceeding. I think it would have</p> <p>25 to go through them, not through me. That's just a collegial</p>	<p>1 other than this but, you know, I am working on other cases,</p> <p>2 and in the context of that I read their comments, and I made</p> <p>3 some replies in some reports. But I don't -- I just -- it</p> <p>4 would help me if you had me look at something. I'm going on</p> <p>5 my memory. It's just a little tough.</p> <p>6 Q All I can ask you to do, Doctor.</p> <p>7 When you say you made some replies in some</p> <p>8 reports, are those expert witness replies?</p> <p>9 A Yes. It's not public.</p> <p>10 Q Are these the ones you submitted in Australia?</p> <p>11 A Yeah, I believe that I did, but I just can't</p> <p>12 remember -- I have read it, and I have thought about it, and</p> <p>13 I thought that I responded to it, but I just can't remember</p> <p>14 the details.</p> <p>15 Oh, well, maybe one thing I can remember is</p> <p>16 that -- well, you know what? I'm going from my memory, so I</p> <p>17 just want to be -- I just can't remember details right now.</p> <p>18 Q Sure. What's your best recollection?</p> <p>19 A I just can't -- I can't remember right now what I</p> <p>20 wrote.</p> <p>21 Q Okay. Are you on page 7 of your report?</p> <p>22 A Yeah.</p> <p>23 MR. JACKSON: When you say "report," do you mean</p> <p>24 the article?</p> <p>25</p>

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<p style="text-align: right;">Page 22</p> <p>1 BY MR. THOMAS:</p> <p>2 Q I need to start over because I got the wrong</p> <p>3 page. Would you go to Exhibit 1, please, and page 10.</p> <p>4 A Oh, okay.</p> <p>5 Q Page 10 has a Figure 4 that has four categories</p> <p>6 of images marked A through E. What's the purpose of</p> <p>7 Figure 4?</p> <p>8 A Would you like me to talk through the message in</p> <p>9 Figure 4? Is that what you're asking me?</p> <p>10 Q That's right.</p> <p>11 A So in Panel A -- and again, this is Dr. Rogers'</p> <p>12 experiments. But in Panel A, these are SEM images of the</p> <p>13 explanted fibers from the AMS mesh, and she focused on</p> <p>14 what's called an area of interest, which is that white box.</p> <p>15 And that area of interest is exposed to X-rays, and then in</p> <p>16 response you get photoelectrons that you can basically use</p> <p>17 to determine the composition of what -- of that surface in</p> <p>18 that small box.</p> <p>19 Q What does it mean for untreated and scraped?</p> <p>20 A That's defined in the paper. Let me give you a</p> <p>21 precise definition.</p> <p>22 So the untreated, basically -- it wasn't scraped.</p> <p>23 We just -- Dr. Iakovlev literally -- my understanding was,</p> <p>24 he explanted the fibers from the mesh under the microscope,</p> <p>25 and he didn't do the dissection. And then the scrape -- he</p>	<p style="text-align: right;">Page 24</p> <p>1 don't see any nitrogen. So that would suggest there's no</p> <p>2 protein.</p> <p>3 Q What's the atomic percentage figure on the -- I</p> <p>4 guess that's the -- on that axis?</p> <p>5 A Well, that's the percentage of each atom that's</p> <p>6 in the spectra. So it's 80 percent carbon, 15 percent --</p> <p>7 it's the percentage of each atom.</p> <p>8 Q Do you expect, do all these add up to</p> <p>9 100 percent?</p> <p>10 MR. JACKSON: Objection, form.</p> <p>11 A I think so, but the raw data are in the</p> <p>12 supplement.</p> <p>13 BY MR. THOMAS:</p> <p>14 Q I'll get to that in just a minute.</p> <p>15 A You know, it's the percentage of the total of</p> <p>16 everything that comes off the surface.</p> <p>17 Q Okay. What is Panel C?</p> <p>18 A So in Panel C we calculated the ratios of each of</p> <p>19 those atoms. So its oxygen to carbon -- so Panel C is</p> <p>20 basically calculated from Panel B. That would be oxygen to</p> <p>21 carbon, nitrogen to carbon and nitrogen to oxygen ratios.</p> <p>22 Q Why do you do that?</p> <p>23 A Well, the purpose here was to see, again, the</p> <p>24 nitrogen to carbon and nitrogen to oxygen ratios go way down</p> <p>25 after scraping, which basically the same point here is to</p>
<p style="text-align: right;">Page 23</p> <p>1 did the microscopic dissection. So that would be the</p> <p>2 difference between the two groups.</p> <p>3 Q Okay.</p> <p>4 A So what's shown in Panel D, those are the --</p> <p>5 those are the peaks that come off, and there's a</p> <p>6 mathematical analysis that Dr. Rogers did for those peaks to</p> <p>7 actually come up with what's shown in Panels B, C and E.</p> <p>8 Sorry, did you --</p> <p>9 Q Just to make it clear, Panel D is the XPS</p> <p>10 testing?</p> <p>11 A Yeah. So Panel D is the emission spectra. So in</p> <p>12 Panel D you're looking at the energy of those photoelectrons</p> <p>13 that come off the surface, and so you get these</p> <p>14 distributions. And then those raw data are analyzed to</p> <p>15 prepare the plots in Panels B, C and E.</p> <p>16 Q What is the data that's represented in Panel B?</p> <p>17 A So the emissions spectra tell us something about</p> <p>18 both the specific atoms that are on the surface as well as</p> <p>19 the binding states. So in Panel B, this is, we show,</p> <p>20 carbon, oxygen and nitrogen. And the point in Panel B is</p> <p>21 that the untreated fibers had nitrogen and oxygen, as you</p> <p>22 would expect, because these weren't treated, right, so there</p> <p>23 were -- again, the purpose of the scraping that Dr. Iakovlev</p> <p>24 did was to remove the protein, right, and so you would see</p> <p>25 oxygen and nitrogen on the surface, but after scraping we</p>	<p style="text-align: right;">Page 25</p> <p>1 show that your scraping is removing the proteins, but</p> <p>2 there's still oxygen on the surface. So the only</p> <p>3 explanation for that would be oxidation. That's the</p> <p>4 message.</p> <p>5 Q Just to nail this down, is there any purpose</p> <p>6 other than to show the effect of the scraping for Panels B</p> <p>7 and C?</p> <p>8 A Well, it's not quite that black and white. I</p> <p>9 mean, I think -- the purpose of doing the scrape and the</p> <p>10 untreated is to show that, you know, before cleaning there's</p> <p>11 protein on the surface, and then after cleaning the protein</p> <p>12 is almost completely removed. There's very little nitrogen.</p> <p>13 In a lot of samples we didn't see any nitrogen, but there's</p> <p>14 still oxygen. And so the question then is, where does that</p> <p>15 oxygen come from? And what we believe is, it's coming from</p> <p>16 oxidation because there's no nitrogen on the surface, which</p> <p>17 would imply there's no protein.</p> <p>18 So that's why we did both was to look at the</p> <p>19 change, you know, to try to be rigorous about it. That's</p> <p>20 why we did both.</p> <p>21 Q What's the purpose of Panel E?</p> <p>22 A So Panel E shows the bonding configurations.</p> <p>23 Q What is a bonding configuration?</p> <p>24 A So if we look at mechanism of degradation of</p> <p>25 polypropylene. You would expect carbonyl groups, which is</p>

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<p>1 the C over on the left. That's the carbonyl.</p> <p>2 And then the other binding configuration is what</p> <p>3 Dr. Rogers would call carboxylate, and this is similar to</p> <p>4 the hydroperoxide degradation product.</p> <p>5 So the point here is to show that before and</p> <p>6 after scraping we see both of those. Again -- and this is a</p> <p>7 point that, you know, Dr. Thames has made in his work about</p> <p>8 the protein. Proteins have carbonyl and carboxylate bonds.</p> <p>9 So if you have protein on the surface, you would expect to</p> <p>10 see quite a bit of bonding, which we do. But even after</p> <p>11 that protein has been removed manually, and then you don't</p> <p>12 see any nitrogen, you still see these carboxylate and</p> <p>13 carbonyl groups. That's the purpose. So it's further</p> <p>14 supporting what we saw in Panels B and C. We see the types</p> <p>15 of bonds that you would see for oxidized polypropylene even</p> <p>16 after the protein has been removed.</p> <p>17 Q What's the significance of the carbonyl numbers</p> <p>18 standing alone?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q Or do you have to look at them side by side in</p> <p>22 order to make --</p> <p>23 A Oh, no -- well, how do I answer that? I'm going</p> <p>24 to try to answer your question. If you don't like it, try</p> <p>25 again. I won't be offended. I'm trying to deal with this</p>	<p>1 that it's oxidized. I think having the untreated groups</p> <p>2 strengthens the rigor of that conclusion. That's the way I</p> <p>3 would answer your question.</p> <p>4 So I do think it stands alone, but I like the way</p> <p>5 I present it in the paper where we do both.</p> <p>6 Q What is the takeaway from Panel E?</p> <p>7 A Panel E. Well, the takeaway would be that after</p> <p>8 you remove the protein, you still see carbonyl and</p> <p>9 carboxylate bonds that are consistent with the degradation</p> <p>10 products of oxidized polypropylene.</p> <p>11 Q Let's go to page 4 of Exhibit 2. Keep that page</p> <p>12 open. You're going to need it.</p> <p>13 A Okay. Page 4, okay.</p> <p>14 Q Do you have that in front of you?</p> <p>15 A Yes.</p> <p>16 Q Do you see Table S6?</p> <p>17 A Yes.</p> <p>18 Q Table S6, page 4, Exhibit 2, is titled "Summary</p> <p>19 of relative amounts (percentage) of the various C 1S bonding</p> <p>20 configurations present on scraped fibers."</p> <p>21 A That's right.</p> <p>22 Q And that is the basis for the scraped fibers</p> <p>23 figure in Figure E on page 10 of Exhibit 1; correct?</p> <p>24 A That's correct.</p> <p>25 Q And S6 is where Ms. Rogers has recorded the data</p>
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<p>1 in a rigorously scientific way.</p> <p>2 Q Maybe I can help you a little bit.</p> <p>3 MR. JACKSON: He was going to answer the</p> <p>4 question.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q Fine. I'm just trying to make it easier on him.</p> <p>7 Go ahead.</p> <p>8 A The reason we did both groups is because I think</p> <p>9 it's scientifically more rigorous to look at the change.</p> <p>10 So you could just -- you could just clean the</p> <p>11 fiber and see carbonyl and carboxylate on the surface and</p> <p>12 conclude that it oxidized, but I think it's more rigorous to</p> <p>13 look at the untreated fiber as well, where you would expect</p> <p>14 to see a lot of carbonyl and a lot of carboxylate, which we</p> <p>15 do. Okay, there's protein on the surface. When I remove</p> <p>16 what I believe to be protein, those bonds come down, which I</p> <p>17 would expect, but they're still there.</p> <p>18 So I think it's -- I prefer to really talk about</p> <p>19 it like it is in the paper, discussing it in its totality.</p> <p>20 And the reason we did those controls was to really give a</p> <p>21 good rigorous analysis and scientific perspective on what we</p> <p>22 did.</p> <p>23 So I would say if I look at -- I know it's a long</p> <p>24 answer. But the fact that I see carbonyl on a scraped fiber</p> <p>25 would tell me -- this shows no nitrogen -- I would conclude</p>	<p>1 that she collected from her XPS; correct?</p> <p>2 A Yes.</p> <p>3 Q And if you looked at Table 6 on page 4 of Exhibit</p> <p>4 Number 2 where it says, 288 eV, that's the XPS column for</p> <p>5 carbonyl group; correct?</p> <p>6 A Yes.</p> <p>7 Q And of the five measurements she took, three were</p> <p>8 nondetect; correct?</p> <p>9 A That's right.</p> <p>10 Q And then she recorded measurements for fibers 23</p> <p>11 and 24. At the bottom is a column for mean plus or minus</p> <p>12 SD. What does that mean?</p> <p>13 A That's the mean plus or minus the standard</p> <p>14 deviation of those five numbers.</p> <p>15 Q What's the purpose for including that column in</p> <p>16 this kind of table?</p> <p>17 A You mean the row?</p> <p>18 Q Yes, the row. I'm sorry.</p> <p>19 A Well, we calculate the average in the standard</p> <p>20 deviation so we can compare the different groups. We can</p> <p>21 quantitatively compare the groups.</p> <p>22 Q From an analytical perspective, what's the</p> <p>23 meaning of the mean plus or minus the standard deviation for</p> <p>24 the carbonyl group, which is .4 plus or minus .6?</p> <p>25 A Well, that would be the standard deviation of the</p>

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<p style="text-align: right;">Page 30</p> <p>1 measurement. It's to measure the spread of the distribution</p> <p>2 of the data.</p> <p>3 Q And so .4 is the mean --</p> <p>4 A Yes.</p> <p>5 Q -- of the values; correct?</p> <p>6 A That's right.</p> <p>7 Q And .6 is the standard deviation or the error</p> <p>8 rate; correct?</p> <p>9 A I don't know if I'd call it error. It's the</p> <p>10 distribution of the samples.</p> <p>11 So we have -- like you pointed out, there were</p> <p>12 three of them that basically were zero. We couldn't see</p> <p>13 anything. It's probably not zero, but practically speaking,</p> <p>14 it's zero. We couldn't measure it. So for two of them we</p> <p>15 measured it. We averaged them together to give -- that's</p> <p>16 what we did.</p> <p>17 So there's a distribution of measurements.</p> <p>18 That's what's reflected by the standard deviation.</p> <p>19 Q What does it mean when the measurement is .4 plus</p> <p>20 or minus .6? What does it mean to you as a chemist looking</p> <p>21 at this data?</p> <p>22 A It's the spread of the distribution.</p> <p>23 Q Does it tell anything to you about the validity</p> <p>24 of the data?</p> <p>25 A What do you mean "the validity of the data"?</p>	<p style="text-align: right;">Page 32</p> <p>1 spread of the distribution.</p> <p>2 I explain in the paper how we did that. I mean,</p> <p>3 it's just a measure of the spread of the distribution. I'm</p> <p>4 not really sure what you're asking.</p> <p>5 Q Can you answer the question?</p> <p>6 A I'm trying to, but I'm not really sure what</p> <p>7 you're asking me.</p> <p>8 Q In reporting compiled data like you have here,</p> <p>9 when you subject it to the mean versus the standard</p> <p>10 deviation, don't you want to have the mean to be greater</p> <p>11 than the standard deviation in order to have reportable</p> <p>12 data?</p> <p>13 MR. JACKSON: Objection, form.</p> <p>14 A But that doesn't -- no, I don't agree with what</p> <p>15 you're saying. I mean, that's a calculation of the data to</p> <p>16 enable comparisons between groups. The data stands as it</p> <p>17 is, you know. I said there's three of them we did not</p> <p>18 detect carboxylate. Two of them we did. From that</p> <p>19 distribution, we can calculate mean and the standard</p> <p>20 deviation, but we -- it doesn't detract from the data. The</p> <p>21 data are the data. They're distributed as they are.</p> <p>22 This is just a means for modeling the data or</p> <p>23 explaining it. It doesn't detract from the data.</p> <p>24 Q Why didn't you report, in Exhibit Number 1, the</p> <p>25 fact that the mean was less than the standard deviation?</p>
<p style="text-align: right;">Page 31</p> <p>1 Q The accuracy of the data as reported.</p> <p>2 MR. JACKSON: Objection, form.</p> <p>3 A I mean, the data that are reported. There are</p> <p>4 five measurements for the amount of carbonyl on each of the</p> <p>5 fibers. That's what reported. This is a statistical</p> <p>6 calculation.</p> <p>7 The data are reported as they are, and some --</p> <p>8 I'm going to say zero, even though, just to make it easier.</p> <p>9 It's not zero. It's some number that was so small we</p> <p>10 couldn't measure it, but we'll call it zero.</p> <p>11 Three of them we didn't see the carboxylate, and</p> <p>12 two of them we did. So what that tells me is that those</p> <p>13 regions, those very small regions that were probed, after</p> <p>14 removing the protein, what we thought was the protein, it</p> <p>15 could have removed some of the oxidized polypropylene.</p> <p>16 Maybe that particular region didn't see much oxidation. We</p> <p>17 don't know, but we couldn't measure oxidation. We didn't</p> <p>18 see it. When I say we couldn't measure it, we didn't</p> <p>19 measure the presence of the carbonyl on those three regions.</p> <p>20 That's what it means.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q Doctor, in statistical analysis, in order to have</p> <p>23 reportable data, don't you want the mean to be greater than</p> <p>24 the standard deviation?</p> <p>25 A I mean, standard deviation, it's a measure of the</p>	<p style="text-align: right;">Page 33</p> <p>1 A I mean, I wouldn't normally report that. I mean,</p> <p>2 we did the -- we tested -- we compared the groups using</p> <p>3 different tests, and we plotted it. We showed the standard</p> <p>4 deviation. It's just a means of characterizing the</p> <p>5 distribution.</p> <p>6 I mean, if you have a distribution centered at</p> <p>7 zero, then the means is going to be zero, and the</p> <p>8 distribution is going to be -- it's an analysis technique.</p> <p>9 It's not -- you can't control how the data distributed, how</p> <p>10 it is distributed.</p> <p>11 Q But the meaning of the data is impacted by the</p> <p>12 mean compared to the standard deviation; correct?</p> <p>13 A Well, the statistical testing is -- no, no. When</p> <p>14 I did the -- I'd have to go back and look at exactly what I</p> <p>15 did.</p> <p>16 We compared distributions. This is just written</p> <p>17 here as a means for the reader to, you know, get some kind</p> <p>18 of understanding of how the data are distributed, but it</p> <p>19 doesn't impact it. The data are the data.</p> <p>20 Q Next column on Table S6, again, which was used</p> <p>21 for Table E in Exhibit 1; correct?</p> <p>22 A You know, Figure 4E, that's what you mean, right?</p> <p>23 Q Correct.</p> <p>24 A Yeah, okay.</p> <p>25 Q It says, "287 eV, RC COOH." What does that</p>

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<p>1 represent?</p> <p>2 A Well, it's just the nature of that carboxylate</p> <p>3 bond.</p> <p>4 My understanding -- again, this is Dr. Rogers'</p> <p>5 work. But, you know, my understanding is, you can basically</p> <p>6 see that it's -- 287 electron volts is consistent with</p> <p>7 carboxylate type of bonding where you have a COOH -- and it</p> <p>8 doesn't tell you the actual details of the bond, but you</p> <p>9 know that you have that kind of configuration where you have</p> <p>10 carbon bonded to oxygen bonded to oxygen bonded to hydrogen.</p> <p>11 There could be several different types of bonding</p> <p>12 configurations, but it has this general structure.</p> <p>13 So it's just too difficult to, you know, say</p> <p>14 exactly what the bonding configuration is, but it's some</p> <p>15 form of this.</p> <p>16 Q Okay. Now, Doctor, if you look at S6 under the</p> <p>17 carboxylate bond column, they record values for fibers 5 and</p> <p>18 8; correct?</p> <p>19 A 5 and 8, yeah. 2.5 and 2.3, is that what you</p> <p>20 mean?</p> <p>21 Q That's correct. If you go to page 2 of Exhibit 2</p> <p>22 --</p> <p>23 A Yeah.</p> <p>24 Q Go to page 2 of Exhibit 2.</p> <p>25 A Okay.</p>	<p>1 Dr. Rogers did that work. She would be the one to answer</p> <p>2 details about that.</p> <p>3 It's not -- I agree that it's not labeled in the</p> <p>4 diagram.</p> <p>5 Q And you can't see a peak that resembles 2.5 in a</p> <p>6 carboxylate area, can you?</p> <p>7 MR. JACKSON: Objection, asked and answered.</p> <p>8 A Yeah, I mean, I think I answered it. You know,</p> <p>9 it's very small. I'd have to look at her analysis of how</p> <p>10 she did that.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q Okay. The same question for fiber 8 in Table S6.</p> <p>13 It shows a carboxylate peak of 2.3?</p> <p>14 A Yes.</p> <p>15 Q If you look at fiber 8 in Figure S2 on page 2 of</p> <p>16 Exhibit 2, there's no carboxylate peak of 2.3 appearing in</p> <p>17 that image as well?</p> <p>18 A Same answer for number 5. I mean, again, she</p> <p>19 didn't label it. I'd have to look at her analysis to figure</p> <p>20 out what she did there.</p> <p>21 Q Did you -- did you prepare Figure E -- Figure 4E</p> <p>22 on page 10 of Exhibit 1?</p> <p>23 A I think so. I know I prepared Figure 4. I don't</p> <p>24 know. I can't remember if I did it or if Anne did it.</p> <p>25 Q Would you agree with me that Figure 4E includes</p>
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<p>1 Q Do you have that?</p> <p>2 A Yeah.</p> <p>3 Q And page 2 of Exhibit 2 shows the XPS images on</p> <p>4 which the author relied to generate the figures that are</p> <p>5 contained in Table S6; correct?</p> <p>6 A Yes.</p> <p>7 Q And under scraped fiber, Figure S2, there are</p> <p>8 images for Figures 5 and 8; correct?</p> <p>9 A Yes.</p> <p>10 Q And on S6 on page 4 for fiber 5, it shows a</p> <p>11 carboxylate bond value of 2.5. Do you see that?</p> <p>12 A Yeah.</p> <p>13 Q If you look at fiber 5 on page 2, there is no</p> <p>14 carboxylate peak of 2.5. Do you agree with that?</p> <p>15 A I don't know. She didn't label it. She</p> <p>16 prepared -- Dr. Rogers prepared these figures. I don't know</p> <p>17 that I would say it's not there. Just, it's not labeled.</p> <p>18 Q Do you see anything that resembles a carboxylate</p> <p>19 peak of 2.5 on Figure 5?</p> <p>20 A I can't tell by looking at this resolution. I'm</p> <p>21 having a hard time seeing it.</p> <p>22 Q You can't see it?</p> <p>23 A Yeah, again, it's not my data. You know, Dr.</p> <p>24 Rogers did this analysis. There's an analysis that's done</p> <p>25 of these data that you have to deconvolute the peaks, and</p>	<p>1 the values 2.5 for fiber 5 and 2.3 for fiber 8 in the bar</p> <p>2 chart for the carboxylates?</p> <p>3 MR. JACKSON: Objection to form.</p> <p>4 A Those are the numbers that are plotted in the</p> <p>5 panel.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q Okay. And do you know the statistical impact of</p> <p>8 removing those values from what you show in 4E?</p> <p>9 MR. JACKSON: Objection to form.</p> <p>10 A I haven't looked at that. I relied on Dr. Rogers</p> <p>11 for this analysis, so I'd have to go back to her and discuss</p> <p>12 this with her. We calculated -- Anne and I did this</p> <p>13 together. I can't remember who did what. We were relying</p> <p>14 on the numbers that she provided in the table.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q And the table you're referring to, Table S6?</p> <p>17 A S6, yeah. We didn't go back and -- this is</p> <p>18 her -- this is what she did. She did the analysis of the</p> <p>19 XPS. So we were relying on her analysis, so I'd have to go</p> <p>20 back to her and discuss that with her.</p> <p>21 Q Since you wrote this paper, you've become aware</p> <p>22 that both Dr. Thames and Dr. McLean have raised this</p> <p>23 criticism of this paper, haven't you?</p> <p>24 MR. JACKSON: Objection to form.</p> <p>25 A I haven't heard -- I don't remember seeing this</p>

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<p>1 point. They wrote some other things about it. They -- I</p> <p>2 mean, they wrote other things. I've never seen this,</p> <p>3 though.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q Since the publication --</p> <p>6 A Just to clarify, this is the first time I've been</p> <p>7 aware of this viewpoint.</p> <p>8 Q Since publication of the Talley paper, have you</p> <p>9 had discussions with -- is it Dr. Rogers?</p> <p>10 A Yes.</p> <p>11 Q -- with Dr. Rogers about the data in Table 6 as</p> <p>12 compared to the XPS on page 2 of Exhibit 2?</p> <p>13 A I haven't discussed this with her for a while,</p> <p>14 probably since we wrote the paper.</p> <p>15 Q Okay. Staying on page 4 of Exhibit 2, who</p> <p>16 prepared the tables in S4, S5 and S6?</p> <p>17 A Dr. Rogers produced these. I mean, I may have --</p> <p>18 I can't remember who did -- I may have made the table based</p> <p>19 on the numbers that she gave us, but she produced those</p> <p>20 numbers.</p> <p>21 Q Okay. Who designed the tables, for lack of a</p> <p>22 better word? Who came up with the format for the tables?</p> <p>23 A Dr. Rogers.</p> <p>24 Q Do you see the column on S4 of 284.8 eV?</p> <p>25 A Mm-hmm.</p>	<p>1 overlap. Like I said, there are methods that have been --</p> <p>2 that are used for this. I don't remember the details of</p> <p>3 those right now, but it's a pretty standard approach.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q Okay.</p> <p>6 A Again, with XPS, this is again Dr. Rogers' work.</p> <p>7 And I've published other papers with her on XPS, and she did</p> <p>8 the separation of the peaks.</p> <p>9 Q In Tables 4, 5 and 6, the last column is 284.3</p> <p>10 eV, and there's no description of what that area is. Do you</p> <p>11 know what that is?</p> <p>12 A So my understanding, that particular peak is</p> <p>13 often what people refer to as adventitious carbon. I think</p> <p>14 it's in the paper. Let me see if I can find it here.</p> <p>15 Q I'm not familiar with that term. What did you</p> <p>16 call it, adventitious?</p> <p>17 A I think the technical term is "adventitious."</p> <p>18 Let me see if it's discuss in here, and then I can give you</p> <p>19 a more precise answer. Maybe we didn't discuss it.</p> <p>20 Q I don't remember seeing it.</p> <p>21 A Basically, I think the best way I can answer that</p> <p>22 is, it's some form of carbon bond that we can't attribute.</p> <p>23 It's difficult to say exactly which bonding configuration it</p> <p>24 could be. So it's a carbon bond, but we don't -- like with</p> <p>25 these other bonds we can say it's carbonyl or carboxylate,</p>
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<p>1 Q It's labeled "CH." What does CH mean?</p> <p>2 A Well, that would be the percent of carbon in that</p> <p>3 carbon hydrogen bonding configuration. So that would be</p> <p>4 like a hydrocarbon bond. CH is what percentage of the</p> <p>5 carbon is bound to the hydrogen. The carbon bond is what</p> <p>6 percentage of your hydrogen bonds, is my understanding.</p> <p>7 Q And you mentioned before the concept of</p> <p>8 deconvolution. What is that?</p> <p>9 A Well, my understanding is, you have these</p> <p>10 overlapping peaks, you know, and these are distributions of</p> <p>11 energy. So they overlap in their mathematical methods that</p> <p>12 you can use to determine, you know, which peak corresponds</p> <p>13 to which type of bond or atom. That's the type of work</p> <p>14 that -- that's what Dr. Rogers does.</p> <p>15 Q Do you consider yourself an expert in the area of</p> <p>16 deconvolution?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 A Well, this is -- this is a method that -- I mean,</p> <p>19 I think I've used it before where you have it any kind of</p> <p>20 overlapping peaks and any kind of analysis. We can see this</p> <p>21 in GPC or HPLC or different chromatography. You can have</p> <p>22 these overlapping peaks. So you have to find a way to</p> <p>23 calculate which is which because the peaks -- I'm not</p> <p>24 explaining it very well.</p> <p>25 You have to be able to separate that region of</p>	<p>1 but we can't say specifically which type of carbon bond</p> <p>2 probably because of overlapping peaks. That's my</p> <p>3 understanding.</p> <p>4 So I would say that it's a carbon bond, but we</p> <p>5 can't provide the details, so we listed it just because --</p> <p>6 the numbers need to add up. We listed everything that we</p> <p>7 saw. It's some form of carbon bond that we don't know the</p> <p>8 details about. I would probably say it that way.</p> <p>9 Q Would you defer to Dr. Rogers for an answer on</p> <p>10 that?</p> <p>11 A Yeah, she could give a more -- Dr. Rogers could</p> <p>12 give a more maybe detailed answer on that. I mean, I think</p> <p>13 she would say the same thing. We just don't -- it's a</p> <p>14 limitation of the method. You can't -- you see a peak</p> <p>15 there, but ascribing that to a specific bonding</p> <p>16 configuration is challenging, so we just report the number</p> <p>17 at the peak.</p> <p>18 That's why we report it. Like you can see in the</p> <p>19 table, we don't list a bonding configuration because we</p> <p>20 don't know.</p> <p>21 Q If you look at page 1 of Exhibit 2, at page 1 of</p> <p>22 Exhibit 2 right in the middle of the page it says, "The</p> <p>23 energy scales at the high-resolution spectra were calibrated</p> <p>24 to place CH₂ bonding in the carbon 1s spectrum at 284.8 eV."</p> <p>25 Do you see that?</p>

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<p>1 A Yeah.</p> <p>2 Q And we go back now to page 4 of the same exhibit,</p> <p>3 you see 284.8 eV. It says, "CH" as opposed to "CH2." Are</p> <p>4 those the same?</p> <p>5 A I think so. I think the CH2 bonding, I think</p> <p>6 what that's referring to is a methyl group, which would be a</p> <p>7 carbon bonded to two other carbons bonded to hydrogens. So</p> <p>8 I think these are the -- I think what she's saying here is</p> <p>9 that basically the scale was calibrated so that those methyl</p> <p>10 carbons are showing up here at 284.8. I think it's</p> <p>11 consistent. That's my understanding.</p> <p>12 Q Has anybody ever told you the column that's</p> <p>13 marked "CH" should be "CH2," and the column that's left</p> <p>14 blank should be "CH"?</p> <p>15 A I've not heard that before. Yeah, I'm not --</p> <p>16 Q Do you know why that wouldn't be true?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q Does that sound implausible or impossible to you,</p> <p>20 as a person involved in this study or as a person with</p> <p>21 knowledge of this test?</p> <p>22 MR. JACKSON: Objection to form.</p> <p>23 A Well, I think as I answered you before, it's not</p> <p>24 consistent with my understanding of the test.</p> <p>25 My understanding is that this is a carbon</p>	<p>1 that we can't say what the exact nature of the bond is.</p> <p>2 Q If you look at Table S4, fiber 9.</p> <p>3 A Yeah.</p> <p>4 Q If you go across, those columns should add up to</p> <p>5 about 100; right?</p> <p>6 MR. JACKSON: Objection to form.</p> <p>7 A I think they should, yeah.</p> <p>8 BY MR. THOMAS:</p> <p>9 Q If you add them up, they add up to 104.8. Do you</p> <p>10 have any explanation for that?</p> <p>11 A No. I'd have to look at that.</p> <p>12 Q Would you defer to Dr. Rogers for her explanation</p> <p>13 of that, or could you answer that question?</p> <p>14 A I would have to talk to her to find out whether,</p> <p>15 you know, that was in what she gave me or whether, when I</p> <p>16 typed the table out in the supplement. I don't know. I'd</p> <p>17 have to check. I'd have to go back and talk to her. I</p> <p>18 couldn't answer that right now.</p> <p>19 Q Let's go back to page 2 of Exhibit 2. Page 2 of</p> <p>20 Exhibit 2 are the XPS -- do you call them spectra or images?</p> <p>21 What do you call them?</p> <p>22 A Spectra.</p> <p>23 Q -- spectra that Dr. Rogers took. You mentioned</p> <p>24 the concept of deconvolution.</p> <p>25 Do you see any deconvolution in any of the images</p>
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<p>1 hydrogen bond and this is some form of carbon bonding</p> <p>2 configuration that we can't -- I mean, if we could ascribe</p> <p>3 this to a specific bonding configuration, we would have done</p> <p>4 that. That's my understanding. I'm going to look at it</p> <p>5 more. I hadn't heard that before.</p> <p>6 Q So just to be clear, the first one you mentioned</p> <p>7 is the CH, 284.8. The second one you described was the last</p> <p>8 one, which was 284.3, which is the one not labeled in the</p> <p>9 exhibit; correct?</p> <p>10 A Yeah, and I think we didn't label it because,</p> <p>11 again, we can't say with certainty what that bonding</p> <p>12 configuration is. It's an observation that we needed to</p> <p>13 report, but we did not assign a bonding configuration</p> <p>14 because we weren't confident in that. It's part of the</p> <p>15 total signal that came of the fiber, so we reported it.</p> <p>16 Q Okay. So in Figures 4 and 5, if you note, that</p> <p>17 you have four nondetects in the last unlabeled column and</p> <p>18 then values of 21.9 and 23.5.</p> <p>19 Do you have any explanation for a nondetect in 4</p> <p>20 and a value of over 20 percent for the fiber 17?</p> <p>21 A I'm confused about where you're talking about.</p> <p>22 That table? I don't, other than what I gave you, that it's,</p> <p>23 you know, it's a form a carbon bonding that's -- I would say</p> <p>24 that we don't believe it's carbon and oxygen bonding like</p> <p>25 the first two columns, but it's some form of carbon bonding</p>	<p>1 that are on page 2 of Exhibit 2?</p> <p>2 A Let me be more specific about my answer. I</p> <p>3 thought this was addressed. I can't seem to find what I'm</p> <p>4 looking for.</p> <p>5 These are -- my understanding, these are the raw</p> <p>6 data, so these are just showing the peaks. I don't think</p> <p>7 we're showing here the analysis to get those peak areas. I</p> <p>8 mean, these are just the peak -- these are the raw data, I</p> <p>9 think. She's not showing that here.</p> <p>10 Q You mentioned that she did deconvolution of the</p> <p>11 samples she tested; correct?</p> <p>12 A I need to find this because I'm relying on my</p> <p>13 memory. Wait a minute. Maybe it's in here. Okay. I think</p> <p>14 I found it. I'm going to be more specific in my answer. I</p> <p>15 don't want to necessarily use this term "deconvolution."</p> <p>16 Basically, what we say in the paper is that the</p> <p>17 curve fitting to extract the contributions of different</p> <p>18 carbon bonding configurations present in the analysis area.</p> <p>19 So she did that curve fitting. I don't believe that's shown</p> <p>20 on these spectra, but she did that analysis to come up with</p> <p>21 the numbers on the table.</p> <p>22 Q Okay.</p> <p>23 A That's what she did.</p> <p>24 Q And the analysis that she used to come up with</p> <p>25 the figures in the table are not available to us today; is</p>

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<p>1 that correct?</p> <p>2 A I don't -- I don't know that -- she has that. I</p> <p>3 don't have that. Dr. Rogers would have that.</p> <p>4 Q And it's not in Exhibit 2?</p> <p>5 A No. That sort of work is beyond the scope of</p> <p>6 what people would typically publish.</p> <p>7 Q So is it your best recollection that Dr. Rogers</p> <p>8 did or did not do deconvolution?</p> <p>9 A Well, like I said, I don't think I want to use</p> <p>10 that term. I want to use the term that's in the paper.</p> <p>11 I'll just be more precise that she did her fitting and</p> <p>12 mathematical analysis to resolve these, in some cases,</p> <p>13 overlapping peaks, and she did her fitting to come up with</p> <p>14 the numbers in the table. That's what she did. Exactly how</p> <p>15 she did that, I don't know.</p> <p>16 Q How is curve fitting different from</p> <p>17 deconvolution?</p> <p>18 A I don't -- it's the same idea. I mean, I was</p> <p>19 using those words interchangeably. I should be really</p> <p>20 precise in that she analyzed the spectra to come up with the</p> <p>21 numbers in the table. She produced -- for the paper we</p> <p>22 showed the spectra, and we listed the results of what she</p> <p>23 called curve-fitting analysis in the paper to come up with</p> <p>24 the numbers.</p> <p>25 The details of how she did that, we probably</p>	<p>1 don't remember the details of exactly how she processed</p> <p>2 those data.</p> <p>3 Q So to answer my question concisely, if you can,</p> <p>4 you defer to Dr. Rogers for the analysis that she used,</p> <p>5 whether it be curve fitting or deconvolution, to come up</p> <p>6 with the data in the tables?</p> <p>7 MR. JACKSON: Objection to form.</p> <p>8 A How do I say this? Yeah, she made those</p> <p>9 decisions. She made the decision about, here's the spectra.</p> <p>10 You can look at the spectra, and you can see there are</p> <p>11 overlapping peaks. And then the XPS field, there are</p> <p>12 various accepted methods. There are, again, mathematical</p> <p>13 approaches where you could address that issue of overlapping</p> <p>14 peaks and come up with -- I mean, she makes some comments</p> <p>15 like that she's using methods that are standard and</p> <p>16 published and known, but she did it, and I don't remember</p> <p>17 the details of what she did.</p> <p>18 Q Okay. On page 2 of Exhibit 2 --</p> <p>19 A Okay.</p> <p>20 Q -- the document says, "A survey spectrum was</p> <p>21 collected from each fiber analyzed. Carbon, oxygen,</p> <p>22 nitrogen and silicon were present on all samples."</p> <p>23 Why would silicon be present on any of these</p> <p>24 samples?</p> <p>25 A Not knowing the manufacturing history -- we</p>
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<p>1 discussed this at some point, but I don't remember the</p> <p>2 details of how she did it.</p> <p>3 Q As you sit here today, do you know any difference</p> <p>4 that you can explain to me between curve fitting and</p> <p>5 deconvolution?</p> <p>6 A I was -- I was using those terms interchangeably.</p> <p>7 The point I was trying to make is that there are overlapping</p> <p>8 peaks in the spectra, and you have to use various</p> <p>9 mathematical methods to resolve those overlapping peaks, and</p> <p>10 that's what Dr. Rogers did. At some point I've been</p> <p>11 referring to that as "deconvolution." At other times I've</p> <p>12 been referring to it as "curve fitting." Basically what I'm</p> <p>13 saying is that there are overlapping peaks, and Dr. Rogers</p> <p>14 did the analysis to address that and come up with the</p> <p>15 numbers in the table. That's what she did.</p> <p>16 Q And for questions about the analysis that Dr.</p> <p>17 Rogers undertook to come up with the numbers in the table,</p> <p>18 you would defer to Dr. Rogers?</p> <p>19 A I would refer to her. I've done this in other --</p> <p>20 I mean, I just published another paper this year doing very</p> <p>21 similar things, using XPS to look at a surface. I did the</p> <p>22 same thing with her there. She typically does the XPS. She</p> <p>23 does the XPS experiments herself. She does the data</p> <p>24 analysis. We talk about it, she explains the limitations.</p> <p>25 She explains what she did, and then we publish it, but I</p>	<p>1 suspected it's something from the manufacturing process, but</p> <p>2 without knowing all of those details, it's hard to say for</p> <p>3 certain, but I would say probably typically, if you find</p> <p>4 something like that on the fiber, that it's going to be</p> <p>5 something related to the manufacturing of the fiber. That's</p> <p>6 our best guess.</p> <p>7 Q Do you know the chemical composition of the</p> <p>8 Boston Scientific meshes you analyzed?</p> <p>9 A The chemical, you mean -- the polypropylene, you</p> <p>10 mean like the formulation?</p> <p>11 Q That's right.</p> <p>12 A I can't remember it. I don't know. If it's a</p> <p>13 Boston Scientific product, I don't know how much detail I</p> <p>14 can give, but it's --</p> <p>15 Q All I want to know is, does the Boston Scientific</p> <p>16 formulation of the polypropylene mesh that you analyzed</p> <p>17 contain silicon?</p> <p>18 A Oh, I see what you're getting at. I don't know.</p> <p>19 We didn't -- that's not in the paper. I don't know.</p> <p>20 Q And you know that the TVT formulation does not</p> <p>21 contain silicon?</p> <p>22 MR. JACKSON: Objection to form.</p> <p>23 A I'm trying to remember. I don't remember the</p> <p>24 formulation off the top of my head, but I can't really say.</p> <p>25</p>

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<p>1 BY MR. THOMAS:</p> <p>2 Q Let me ask you to assume. We've done this</p> <p>3 before. Let me ask you to assume that the TVT formulation</p> <p>4 of polypropylene and its proline does not contain silicon.</p> <p>5 What could be the source of the silicon that appeared in</p> <p>6 your XPS spectra?</p> <p>7 MR. JACKSON: Objection, asked and answered.</p> <p>8 A Well, these are AMS fibers, so it's hard to say.</p> <p>9 I mean, I don't know. I mean, these are AMS fibers. I</p> <p>10 don't know what the formulation of AMS fiber is. We didn't</p> <p>11 look at it.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q Okay. Fiber number 5 that had been scraped</p> <p>14 contained a small amount of chlorine. Any explanation for</p> <p>15 why chlorine might be present on fiber number 5?</p> <p>16 A I would say it's probably similar to the silica</p> <p>17 case. We don't typically -- that would come from something</p> <p>18 in the manufacturing processing, but we don't know the</p> <p>19 source of the chlorine.</p> <p>20 Q Okay.</p> <p>21 A Do you want to take a break for a few minutes?</p> <p>22 Q Sure, whenever you're ready. Let's do that.</p> <p>23 (Recess was taken from 9:45 to 9:51.)</p> <p>24 BY MR. THOMAS:</p> <p>25 Q Dr. Guelcher, was there any consideration given</p>	<p>1 MR. JACKSON: Objection to form.</p> <p>2 A Can I go to my report on that? I don't know if</p> <p>3 that has been entered into evidence, has it?</p> <p>4 Can you ask that again?</p> <p>5 MR. THOMAS: Can you read that back? I'm not</p> <p>6 sure I can remember it that well.</p> <p>7 (Last question was read back.)</p> <p>8 MR. JACKSON: Counsel, he said he'd like to look</p> <p>9 at a copy of his report to possibly answer that</p> <p>10 question. Is that something you could provide him?</p> <p>11 BY MR. THOMAS:</p> <p>12 Q I sure can, if you think that would help him.</p> <p>13 I'm trying to save time.</p> <p>14 A I think it would. As I said, this deposition</p> <p>15 came very quickly.</p> <p>16 Q For me, too.</p> <p>17 A I reviewed the documents, but it helps to have</p> <p>18 things in front of me so I can, you know --</p> <p>19 Q Doctor, I can assure you, we're both under time</p> <p>20 constraints, and I assure you I'm trying to be as efficient</p> <p>21 as I can.</p> <p>22 A No, I understand.</p> <p>23 (Exhibit 3 was marked for identification.)</p> <p>24 BY MR. THOMAS:</p> <p>25 Q I marked as Exhibit No. 3 your copy of the Wave 5</p>
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<p>1 to conducting an FTIR analysis of the AMS explanted mesh?</p> <p>2 A Yes, we discussed it. I can't remember if it's</p> <p>3 explained in the paper.</p> <p>4 The problem was, as these fibers were very small,</p> <p>5 and so we were pretty constrained to -- the advantage of the</p> <p>6 XPS is, you can examine those very small regions of the</p> <p>7 fiber. I think we were really just limited on sample size</p> <p>8 to do the FTIR. We just didn't have much sample. That's</p> <p>9 what I remember.</p> <p>10 Q Okay. Would FTIR have been your first choice?</p> <p>11 A No, I don't think so, because, you know -- I</p> <p>12 think this is in my report. Again, with the FTIR, it's --</p> <p>13 it has been -- you know, Clave brings it up in his paper.</p> <p>14 I've talked about it in when I wrote about Dr. Thames'</p> <p>15 study. FTIR, it's harder to be more conclusive about oxygen</p> <p>16 and nitrogen.</p> <p>17 As I explain in the report, the EDS and the XPS</p> <p>18 are more -- they can tell you about these specific atomic</p> <p>19 concentrations. By testing fibers that have been scraped</p> <p>20 and unscraped, you know, I think XPS is a more specific</p> <p>21 technique. That's why we chose that because we can actually</p> <p>22 look at the amount of nitrogen and the amount of oxygen on</p> <p>23 the surface of the fibers.</p> <p>24 Q Would FTIR of the scraped, explanted AMS mesh</p> <p>25 tell you the extent of your success in cleaning the mesh?</p>	<p>1 report, not the exhibits, just the text of the report.</p> <p>2 A So the question is, would FTIR be a method for --</p> <p>3 it's hard -- I'm going to answer to the best I can.</p> <p>4 Q Sure.</p> <p>5 A So with FTIR I would -- if I did -- maybe I can</p> <p>6 try answering this way.</p> <p>7 If I did FTIR on these scraped fibers, I would</p> <p>8 probably -- I think I would expect to see carboxylate and</p> <p>9 hydroxyl bonds, as we did in the XPS. I would think I would</p> <p>10 see those in the FTIR as well.</p> <p>11 But again, the challenge with the FTIR is that</p> <p>12 there are peaks in the proteins, and there are peaks in the</p> <p>13 oxidized polypropylene that overlap, so it's more difficult</p> <p>14 to say whether it's, you know, specifically from the protein</p> <p>15 or the oxidized polypropylene.</p> <p>16 What the XPS again tells you is the atoms.</p> <p>17 There's so much nitrogen, so much oxygen. That's why we</p> <p>18 chose -- I think FTIR would tell you something, and of</p> <p>19 course we did FTIR in vitro. It's not that we didn't want</p> <p>20 to do it. It's just that we didn't have enough sample.</p> <p>21 Q You relied on your visual observation of the</p> <p>22 scraped AMS explant to satisfy yourself that it had been</p> <p>23 cleaned?</p> <p>24 A I don't think that's -- no, I wouldn't say that.</p> <p>25 I think I answered that earlier. I mean, that's why we</p>

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<p style="text-align: right;">Page 54</p> <p>1 did -- just going back to the paper. That's why we did -- I</p> <p>2 mean, that's why I preferred this more rigorous approach of</p> <p>3 looking at the uncleaned fiber and the scraped in</p> <p>4 considering the differences because -- Dr. Iakovlev cleaned</p> <p>5 it as effectively as he could, but by doing the XPS and</p> <p>6 looking at the atoms and the bonding, you can be much more</p> <p>7 rigorous about it.</p> <p>8 When the nitrogen goes away, I think that's a</p> <p>9 reasonable indication that the protein was removed.</p> <p>10 That's -- so I wouldn't say we relied on visual</p> <p>11 observations. We tested both. That's sort of the basis for</p> <p>12 the conclusions in the paper.</p> <p>13 Q So had you had more sample, would it have been</p> <p>14 your preference to do both FTIR and XPS?</p> <p>15 A We would have liked to have done FTIR. I mean, I</p> <p>16 think in these studies, the more methods you can do, you</p> <p>17 know, reviewers like to see that.</p> <p>18 Like I said, FTIR does give you some information,</p> <p>19 but I think you need other methods in addition to that.</p> <p>20 That's what we attempted to do here.</p> <p>21 Q Okay.</p> <p>22 A To clarify, in-vitro we don't have the</p> <p>23 complication of the protein. FTIR in vitro is a different</p> <p>24 situation. But for explants, as I said in my report, I</p> <p>25 think there are methods that are more specific than FTIR.</p>	<p style="text-align: right;">Page 56</p> <p>1 A Yeah. Those are switched.</p> <p>2 Q Okay. And we decided the XPS and the SEM are</p> <p>3 owned by the University?</p> <p>4 A Yeah. Yeah, those are University resources.</p> <p>5 Q Who owns the FTIR equipment?</p> <p>6 A I'm not sure about that. You'd have to ask Dr.</p> <p>7 Dunn.</p> <p>8 Q Do you know what kind of FTIR equipment he used?</p> <p>9 A I don't know that we go into that in much detail</p> <p>10 in the paper, but...</p> <p>11 Q Did you review any protocols for the FTIR testing</p> <p>12 of the three meshes that are seen in Figure 2 in Exhibit 1?</p> <p>13 A The actual testing the acquisition of the data?</p> <p>14 Q Right.</p> <p>15 A I mean, we talked about it. Dr. Dunn has been</p> <p>16 doing FTIR for a very long time, so he was using methods</p> <p>17 that he's used in the past.</p> <p>18 We didn't necessarily talk about the detailed</p> <p>19 protocol that he used. We talked about the general ideas,</p> <p>20 you know, how he would do the experiment. I mean, I just --</p> <p>21 he has a lot of expertise in that area, so I just relied on</p> <p>22 him to do it. I knew what he was doing, but details of how</p> <p>23 he put the fibers on the instrument, he did all of that.</p> <p>24 Q So these are three different meshes; correct?</p> <p>25 A What are three different meshes?</p>
<p style="text-align: right;">Page 55</p> <p>1 Q Let's go to Exhibit No. 1, please, and go to</p> <p>2 page 7.</p> <p>3 A Okay.</p> <p>4 Q Page 7 in Figure 2 contains FTIR spectroscopy of</p> <p>5 three different meshes over a five-week period; correct?</p> <p>6 A That's right.</p> <p>7 Q And is this testing that people -- Dr. Dunn and</p> <p>8 people under his supervision prepared?</p> <p>9 A Yeah. Dr. Dunn -- to my knowledge, Dr. Dunn ran</p> <p>10 these FTIR spectra.</p> <p>11 Q Okay. And who prepared the text for Figure 2?</p> <p>12 A You mean the caption?</p> <p>13 Q Yeah, bottom of the page on page 7.</p> <p>14 A I would say we wrote that together, probably. I</p> <p>15 mean, it's, you know -- I don't remember who exactly wrote</p> <p>16 it.</p> <p>17 Q Do you see down at the bottom it says, "The</p> <p>18 carbonyl peak is indicated with the black arrow." Do you</p> <p>19 see that?</p> <p>20 A Oh, yeah.</p> <p>21 Q It's a mistake, isn't it?</p> <p>22 A The black arrow, yeah. The carbonyl is the gray</p> <p>23 arrow. It's switched in the caption.</p> <p>24 Q The hydroxyl peak, which is indicated as the gray</p> <p>25 area, is actually the black arrow?</p>	<p style="text-align: right;">Page 57</p> <p>1 Q TVT, ADV and Lynx.</p> <p>2 A Oh, yeah. Yeah, those are the three materials</p> <p>3 that we tested.</p> <p>4 Q And these are three materials that you placed in</p> <p>5 what I'll describe as an oxidated medium?</p> <p>6 A That's right.</p> <p>7 Q And then you took FTIRs before the test began?</p> <p>8 A Yes.</p> <p>9 Q And at week 1, week 3, week 4 and week 5;</p> <p>10 correct?</p> <p>11 A Yeah, that's right.</p> <p>12 Q And do you know how many -- strike that.</p> <p>13 Are you familiar with the term "scaling" as used</p> <p>14 in FTIR?</p> <p>15 A Scaling, that could mean -- what exactly do you</p> <p>16 mean by that?</p> <p>17 Q Do you have any understanding what it might mean</p> <p>18 in the FTIR?</p> <p>19 A It's kind of a broad -- kind of a broad general</p> <p>20 word. I don't -- I'm not sure what exactly you're referring</p> <p>21 to.</p> <p>22 Q That's fine. Do you know who conducted the</p> <p>23 tests, the FTIR tests?</p> <p>24 A Dr. Dunn, I believe.</p> <p>25 Q You mentioned before that it might have been</p>

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<p style="text-align: right;">Page 58</p> <p>1 someone under his direction. Do you know anybody else under</p> <p>2 his direction that might have conducted the test?</p> <p>3 A I don't know. It's been some time. I don't</p> <p>4 know. He would have to answer that. He may have done the</p> <p>5 FTIR spectra himself. He was pretty -- I don't know the</p> <p>6 details of how he actually did it.</p> <p>7 Q Do you know how many scans he ran each week?</p> <p>8 A Other than what's reported in the paper, I don't</p> <p>9 remember those kind of details. Let me see what I wrote.</p> <p>10 We didn't report the number of scans, but again,</p> <p>11 he would have that. I just don't remember how many we did.</p> <p>12 Q Do you know the number of scans that are</p> <p>13 generally regarded as appropriate for reporting FTIR data?</p> <p>14 MR. JACKSON: Objection to form.</p> <p>15 A Not off the top of my head.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q Do you know why you run multiple scans?</p> <p>18 A Well, I mean, I would run multiple scans to --</p> <p>19 you know, that helps you address sort of the error in</p> <p>20 measurement. So I would run multiple scans. I just don't</p> <p>21 know how many he did here. These are details Dr. Dunn would</p> <p>22 have to address.</p> <p>23 Q How many scans would you believe you, Dr.</p> <p>24 Guelcher, believe were appropriate to address the error in</p> <p>25 your measurement?</p>	<p style="text-align: right;">Page 60</p> <p>1 off my memory here -- but it's not related to any of the</p> <p>2 actual bonds that we're looking at in the spectra.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q I understand. Do you have an explanation for</p> <p>5 what happened between week -- from the baseline, week zero,</p> <p>6 and the first week to result in that change in that peak in</p> <p>7 the middle of the week 1 spectra?</p> <p>8 MR. JACKSON: Objection to form.</p> <p>9 A I can't really address that without looking at</p> <p>10 the raw data. Again, this is a published paper. These are</p> <p>11 published data. I said that Dr. Dunn collected all these</p> <p>12 data. I mean, it's kind of hard to go through -- we've seen</p> <p>13 these types of things before.</p> <p>14 BY MR. THOMAS:</p> <p>15 Q Do you know what it is?</p> <p>16 A I think it's carbon dioxide, but I can't remember</p> <p>17 off the top of my head.</p> <p>18 Q Would you defer to Dr. Dunn?</p> <p>19 A Yeah. I know I've seen this before in some of my</p> <p>20 papers where we're looking at isocyanates. Basically,</p> <p>21 sometimes these types of things will happen in the FTIR</p> <p>22 spectra. I can say I don't think this is associated with a</p> <p>23 change in the sample. I think this came up in another</p> <p>24 deposition, to be honest with you. I'm trying to remember</p> <p>25 what I said then, but I don't think it's an actual change in</p>
<p style="text-align: right;">Page 59</p> <p>1 MR. JACKSON: Objection to form.</p> <p>2 A I just don't know off the top of my head. I</p> <p>3 can't remember.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q And what errors can occur in measurement that you</p> <p>6 would need to address with multiple scans?</p> <p>7 MR. JACKSON: Objection to form.</p> <p>8 A I don't know. Just generally speaking, it's just</p> <p>9 good practice just in case there's some artifact in the</p> <p>10 measurement. You run things multiple times. I can't recall</p> <p>11 right now.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q Dr. Guelcher, I want to direct your attention to</p> <p>14 Figure 2, the TVT, which is the top FTIR spectra that's</p> <p>15 listed there.</p> <p>16 A Okay.</p> <p>17 Q Do you see in week 1 that about halfway across</p> <p>18 the scan there's a dip in the spectra? Do you see that?</p> <p>19 A Oh, yeah.</p> <p>20 Q And that is a change from week 1. Do you see</p> <p>21 that?</p> <p>22 MR. JACKSON: Objection, form.</p> <p>23 A Yeah, but I believe you can see peaks like this</p> <p>24 with carbon dioxide. So you basically -- that's not -- we</p> <p>25 can see peaks like that in the spectra -- again, I'm going</p>	<p style="text-align: right;">Page 61</p> <p>1 the material.</p> <p>2 Q Is it a change in the testing environment?</p> <p>3 MR. JACKSON: Objection to form.</p> <p>4 A What do you mean by the environment? Maybe like</p> <p>5 the gas --</p> <p>6 BY MR. THOMAS:</p> <p>7 Q Something about the testing environment that</p> <p>8 altered the FTIR spectra.</p> <p>9 A I just can't remember off the top of my head.</p> <p>10 Q That's fine. Week 3, it looks like that peak</p> <p>11 that we just mentioned in week 1 is gone. Do you see that?</p> <p>12 A Yeah.</p> <p>13 Q And then in week 4 it appears again, but it's</p> <p>14 going a different direction.</p> <p>15 A Yeah, but I don't think this is -- this is -- I</p> <p>16 think you see this in FTIR spectra, and I can't remember the</p> <p>17 details exactly of why it's there, you know. Reviewers</p> <p>18 didn't have a hard time with this. It's not relevant to the</p> <p>19 findings of the carbonyl, and it's in a totally different</p> <p>20 part of the spectra. I mean, it's -- I just don't think</p> <p>21 it's significant. It's not a significant finding. It</p> <p>22 doesn't significantly impact the finding from the FTIR data.</p> <p>23 Q Okay. Doctor, as you look at the TVT mesh, going</p> <p>24 from weeks 1, 2, 3, 4, week 4 in the areas that you're</p> <p>25 looking at, that is, the carbonyl and hydroxyl, week 4 show</p>

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<p style="text-align: right;">Page 62</p> <p>1 no peaks. Do you agree with that?</p> <p>2 A You know, they're not -- if there's a peak there,</p> <p>3 it's not as big as it is in week 5. Week 5 is where we saw</p> <p>4 the peak showing up.</p> <p>5 Q Okay. And you'll agree that the week 4 spectra</p> <p>6 is actually smoother than the spectra from weeks 1 and 3?</p> <p>7 MR. JACKSON: Objection to form.</p> <p>8 A I mean, there's less noise in the --</p> <p>9 BY MR. THOMAS:</p> <p>10 Q Yes.</p> <p>11 A It might appear that way.</p> <p>12 Q Do you have any explanation for that?</p> <p>13 A Again, these are Dr. Dunn's raw data. I can't</p> <p>14 really -- I mean, again, this is peer-reviewed. People</p> <p>15 looked at this and didn't have a problem with it. I mean,</p> <p>16 this is FTIR. You get noisy spectra sometimes.</p> <p>17 Q Is noisy spectra the reason why you do multiple</p> <p>18 scans?</p> <p>19 MR. JACKSON: Objection, form.</p> <p>20 A Could be.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q In any event, you'd defer to Dr. Dunn to answer</p> <p>23 this?</p> <p>24 A I mean, you're going down this line of</p> <p>25 questioning that I'm really -- it's Dr. Dunn's work. It's</p>	<p style="text-align: right;">Page 64</p> <p>1 that you would have showed that this was water confounding</p> <p>2 your FTIR spectra?</p> <p>3 MR. JACKSON: Objection, form.</p> <p>4 A I haven't heard that before. I don't know how</p> <p>5 they could make that opinion without seeing the spectra. I</p> <p>6 haven't seen that.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q You haven't seen that?</p> <p>9 A No.</p> <p>10 Q All right. But any questions in that regard</p> <p>11 would be best directed to Dr. Dunn?</p> <p>12 A You're just going to have to talk to Dr. Dunn</p> <p>13 because that's not -- I didn't do it. I think the question</p> <p>14 that we're going after in the papers was clear, and we</p> <p>15 explained the methods we used, and reviewers accepted it.</p> <p>16 There were no concerns about this. That's why it got</p> <p>17 published.</p> <p>18 And those types of detailed questions about the</p> <p>19 data and how far you ran the spectra, Dr. Dunn would be the</p> <p>20 one that would have to answer that. It's not my data.</p> <p>21 Q If you go to the Lynx mesh in Figure 2, week 4,</p> <p>22 you agree that they show no peaks either at the carbonyl or</p> <p>23 the hydroxyl peak?</p> <p>24 A You know, again, same as before. I don't know</p> <p>25 that I'd say there's no peak, but it's much smaller.</p>
<p style="text-align: right;">Page 63</p> <p>1 kind of hard for me to speculate on these things.</p> <p>2 Q Okay. Now, for all three of these spectra --</p> <p>3 actually, there are 15 spectra, three different devices,</p> <p>4 five spectra for each. The spectra themselves are</p> <p>5 truncated. They're stopped at about the 1,100 level. Do</p> <p>6 you see that?</p> <p>7 A Yeah.</p> <p>8 Q Why is that?</p> <p>9 A Well, again, the peaks that we were interested in</p> <p>10 were the carbonyl and hydroxyl. And just to make it easier</p> <p>11 for the reader to read the paper, in that range of the</p> <p>12 spectrum we're not necessarily expecting changes, so they're</p> <p>13 not shown here.</p> <p>14 Now, whether Dr. Dunn went out to those wave</p> <p>15 numbers, I don't know. But what we tried to show here,</p> <p>16 these are representative spectra to give the reader of the</p> <p>17 paper an idea of the changes that we saw. That's the</p> <p>18 purpose of this figure. So over what range he ran it, I</p> <p>19 don't know. You'd have to talk to him.</p> <p>20 Q Okay. Have you ever seen spectra for the meshes</p> <p>21 that are depicted in Figure 2 that are complete FTIR</p> <p>22 spectra?</p> <p>23 A A can't remember. I don't know.</p> <p>24 Q Do you remember Dr. Thames and Dr. McLean opining</p> <p>25 in their report that had you displayed the additional data</p>	<p style="text-align: right;">Page 65</p> <p>1 Q And then in week 5 there's, at least for the</p> <p>2 Lynx, there's a much larger change than either the ADV or</p> <p>3 the TVT. Do you agree with that?</p> <p>4 A Yeah, that peak is bigger.</p> <p>5 Q Do you have any reason or opinion about why the</p> <p>6 peaks that you found in the Lynx are so much higher and</p> <p>7 bigger than the peaks that you found in either the ADV or</p> <p>8 the TVT?</p> <p>9 A No, that really wasn't the purpose of the paper.</p> <p>10 The purpose of the paper was not to compare meshes. The</p> <p>11 purpose of the paper was to answer the question whether mesh</p> <p>12 stabilized with antioxidants can oxidize. That was the</p> <p>13 question.</p> <p>14 We were not trying to look for differences</p> <p>15 between the meshes. That was -- that's not a question we</p> <p>16 were really addressing.</p> <p>17 Q But does this analysis -- strike that. But the</p> <p>18 three meshes were both subjected to the same conditions?</p> <p>19 A Yeah.</p> <p>20 Q And the same tests?</p> <p>21 A Yeah.</p> <p>22 Q So is it unreasonable to compare the finding in</p> <p>23 week 5 to the TVT to the finding in week 5 to the Lynx?</p> <p>24 A Well, you can make whatever comparison you want,</p> <p>25 but that's not a question we're going after in this study.</p>

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<p>1 That wasn't -- you know, we weren't trying to make 2 comparisons between different types of mesh. 3 We were just -- we know that they're all 4 stabilized with antioxidants, so we were asking the 5 question, can it happen? It happened in all three of them. 6 That's what I can say. 7 Q Okay. Now, based on past litigation, I know that 8 you're aware of the antioxidants that are contained in TVT. 9 A Yes. 10 Q Are you aware of the antioxidants that are 11 contained in Boston Scientific? 12 A I'm aware of them. I don't remember exactly what 13 they were and can't really -- even if I did, I can't really 14 say what they are. I believe that I have seen those 15 formulations. 16 Q Is it different than the TVT? 17 A I can't remember. 18 Q Do the different peaks that you see in weeks 5 19 for the TVT and the Lynx tell you anything about the 20 differences in the mesh? 21 A Again, I think -- I thought I answered that. I'm 22 not willing to -- based on these data, that's not discussed 23 in the paper. That's not a question we were trying to 24 answer. I'm not going to look at these spectra and conclude 25 that there were significant differences because that's not a</p>	<p>1 A It what? 2 Q I haven't talked to you about the Talley paper 3 before. I've never asked you questions about that before. 4 A No, but some other Ethicon attorneys have. 5 Q Not in the context of Talley? 6 A No, but it's the same answer. I've been asked 7 about this medium before. I mean, the medium simulates the 8 microenvironment between the macrophage and the adherent -- 9 well, I didn't answer that very well. It simulates the 10 environment between the macrophage and polypropylene 11 surface. 12 MR. THOMAS: Let me show you Exhibit No. 4. 13 (Exhibit 4 was marked for identification.) 14 BY MR. THOMAS: 15 Q This is the paper that we've talked about before; 16 correct? 17 A Yeah. This isn't a paper. This is a published 18 conference proceedings. 19 Q Just so we're clear, you don't rely upon this 20 test and this data in the opinions that you're giving in 21 this case; correct? 22 MR. JACKSON: Objection to form. 23 A I don't remember if I cited it in the report, but 24 this is a conference proceedings that was published before 25 the paper. So the paper basically, I think, includes all of</p>
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<p>1 question we were testing. That's outside of scope of what 2 we did. 3 Q Okay. 4 A Anybody can look at that and draw any opinion 5 that they want, but that's not my opinion. I don't have an 6 opinion about that. 7 Q That's fine. Now, the analysis that you show in 8 Figure 2, is it fair to describe this as an accelerated 9 oxidation study? 10 MR. JACKSON: Objection, form. 11 A I've answered this before, too, but I don't know 12 that I would use the term "accelerated." 13 I mean, essentially I think the way I've answered 14 this before is that you -- this medium simulates that 15 privileged pocket between the macrophage and the material 16 surface, and so it's essentially like you're exposing the 17 entire material to that privileged environment. 18 So I don't know that I'd call it accelerated. I 19 think what this method does is, it produces hydroxyl 20 radicals, which are reactive oxygen, and so it simulates 21 what can happen in the body. That's what I think has been 22 published about this medium, and I've published other papers 23 on it. We talked about it before. 24 Q That was the prior paper that you presented, 25 different organizations, correct?</p>	<p>1 these data. I haven't looked at it recently, but I believe, 2 just looking at it right now, the paper includes the data in 3 this conference proceedings. 4 So I don't want to say I'm not relying on it, but 5 it's, you know, it's a paper -- most of what's in this 6 abstract is incorporated in the paper. 7 MR. JACKSON: I just want to state for the record 8 this was Exhibit 3 at his last deposition. 9 MR. THOMAS: I understand that. The reason why I 10 asked is because I understood -- 11 THE WITNESS: I'm not sure what you're getting 12 at, I guess. 13 MR. THOMAS: I'm not either. I don't want to 14 plow old ground. 15 THE WITNESS: I understand that. I'm not sure 16 what you're asking. 17 MR. THOMAS: I didn't take the last deposition. 18 I think Mr. Hutchinson did. 19 BY MR. THOMAS: 20 Q Let me back up because I think I may be talking 21 about different things. 22 A Okay. 23 Q There is yet other papers about other work that 24 you did that you presented I think in Europe, and that was 25 the subject of a motion in the Boston Scientific litigation,</p>

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<p style="text-align: right;">Page 70</p> <p>1 and after that time you stopped relying upon that data in 2 your opinions in the case.</p> <p>3 MR. JACKSON: I'm going to object to form of the 4 last question. I think we're getting pretty far afield 5 here. We're talking about a different litigation.</p> <p>6 MR. THOMAS: All I'm trying to do, Tim, is to 7 limit his opinions because -- I don't mean to make it a 8 speech, but I'm trying to shortcut this.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q You did some earlier work that you presented, and 11 we went through the background data. We went through all 12 the stuff.</p> <p>13 A I think I know where you're going.</p> <p>14 Q At some point you stopped relying on that data in 15 your opinions in the case. All I want to do is establish 16 that you haven't changed your mind and are now relying on 17 testing and results that you reported before and presented 18 before that you previously withdrew.</p> <p>19 A I know this is your question on the table. It 20 would really help me out to just deal with this head-on if I 21 could talk with counsel for a few minutes.</p> <p>22 Q Sure.</p> <p>23 MR. JACKSON: Could we take a two-minute break?</p> <p>24 THE WITNESS: I'm not trying to give you a hard 25 time.</p>	<p style="text-align: right;">Page 72</p> <p>1 was in those test data. I don't think we had a lot of the 2 analysis that we presented in this paper.</p> <p>3 Q Exactly right.</p> <p>4 A So the raw data we looked at and did some 5 additional analysis and thinking and submitted paper, a 6 publication which was peer-reviewed and published. So we 7 did not repeat the experiment, but we did more work on the 8 analysis to basically present the paper in a form that could 9 be published.</p> <p>10 Q Right. To be fair, I think the XPS data is new?</p> <p>11 A I believe it is, but I can't remember exactly 12 what was in that report.</p> <p>13 Q And the AMS explant analysis is new?</p> <p>14 A I don't think that was in any test data -- I 15 can't remember. To the best of my knowledge, I believe it's 16 new, but I just can't remember what Dr. Dunn disclosed in 17 his test data.</p> <p>18 Q Okay. Dr. Guelcher, if you look back at Figure 2 19 on page 7, the carbonyl peaks that are there that are 20 mislabeled with the gray arrow, do you know if those 21 carbonyl peaks appear at the same place for each mesh?</p> <p>22 A I'd have to go back and look at the raw data. 23 There are multiple -- there can be multiple carbonyl peaks. 24 I can't remember if they're different for each. 25 Again, that's not what -- we weren't answering</p>
<p style="text-align: right;">Page 71</p> <p>1 MR. THOMAS: I'm not worried about that because I 2 want to make this quick and easy too. Let's go off the 3 record.</p> <p>4 (Recess was taken from 10:22 to 10:32.)</p> <p>5 BY MR. THOMAS:</p> <p>6 Q Doctor, are the FTIR spectra that are on Figure 2 7 of Exhibit No. 1 the result of tests that we've previously 8 discussed in deposition, or have you done a second set of 9 tests?</p> <p>10 A No, we haven't done a second set of tests.</p> <p>11 Q Okay. Just so we're clear -- and I think we 12 talked about this before because I think I asked you 13 questions about it -- some time ago you conducted a 14 five-week oxidation study that you presented at least at one 15 conference and disclosed those opinions in an expert report; 16 correct?</p> <p>17 A That's right.</p> <p>18 Q After the disclosure of those expert opinions, 19 for whatever reason you stopped relying upon the test 20 results in that report for your opinions.</p> <p>21 A Yes. Yeah, I didn't rely on the test data.</p> <p>22 Q Is it fair to understand that now that the data 23 has been published that you are now relying on that data for 24 your opinions in this case?</p> <p>25 A I don't -- well, I don't remember exactly what</p>	<p style="text-align: right;">Page 73</p> <p>1 that question in this paper, so I really don't think we 2 looked at it. We were just looking at that -- well, we 3 explained what we did. 1,500 to 1,750 is where you'll see 4 those carbonyl peaks, and we weren't looking for differences 5 between products or materials.</p> <p>6 Q You agree that an FTIR is designed to generate a 7 fingerprint for a particular substance?</p> <p>8 A I don't know that I'd say it that way. Basically 9 the FTIR gives you information about bonds based on 10 vibration frequencies. But carbonyls -- I mean, I think 11 this has come up in previous depositions -- there can be 12 multiple peaks. This is all even in some of the Ethicon 13 documents that I cite in my report. There can be multiple 14 carbonyl peaks, and we just didn't look for differences 15 between materials.</p> <p>16 Q Would you expect polypropylene in different 17 meshes that are exposed to the exactly the same conditions 18 as you did in your study in Exhibit 1 to display the same 19 carbonyl peak if in fact it was oxidized polypropylene?</p> <p>20 A I'm going to have to go to my report for that 21 one. I know that it's in here.</p> <p>22 I think the best I can answer is like I did. 23 There are multiple species. There are a number of Ethicon 24 documents reporting different carbonyl peaks that could be 25 resulting from different species. I wouldn't necessarily</p>

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<p style="text-align: right;">Page 74</p> <p>1 expect different materials from different manufacturers to</p> <p>2 have different peaks. I can't rule it out. I don't know</p> <p>3 that -- it's just, there's just multiple species, and it can</p> <p>4 be difficult to assign some of them to specific bonds, you</p> <p>5 know, real precisely.</p> <p>6 This goes back to what I was saying about the</p> <p>7 difference between XPS and FTIR. I mean, I can say broadly</p> <p>8 that if the polypropylene is oxidizing based on reaction</p> <p>9 mechanism, I would expect to see carbonyl peaks, and that's</p> <p>10 what we tested in this paper, but we just weren't looking at</p> <p>11 that level of detail for differences between groups.</p> <p>12 Q I want to talk now about the AMS explant that</p> <p>13 Dr. Iakovlev supplied. Do you know how he scraped it?</p> <p>14 A Again, you'd have to talk to him about those</p> <p>15 details. I think you know Dr. Iakovlev's papers, but he</p> <p>16 prefers to work with dry mesh to get around this protein</p> <p>17 cross-linking issue that Dr. Thames referred to.</p> <p>18 So Dr. Iakovlev has been doing it for some time.</p> <p>19 I've seen his microscope. I've seen his lab. Exactly how</p> <p>20 he does that procedure, I don't have the details.</p> <p>21 Q It's fair to understand, from a review of</p> <p>22 Exhibit 1 or Exhibit 2, there's no way for another</p> <p>23 researcher to replicate this cleaning technique. Do you</p> <p>24 agree with that?</p> <p>25 A I don't agree with that. I think he gave enough</p>	<p style="text-align: right;">Page 76</p> <p>1 BY MR. THOMAS:</p> <p>2 Q The first page.</p> <p>3 A Yeah, so we don't describe -- referring back,</p> <p>4 this is just supplemental material. So I think the primary</p> <p>5 description of what he did is in the paper.</p> <p>6 Q Okay. Can you tell how much force he used in</p> <p>7 scraping, from the paper?</p> <p>8 A Well, I mean, I think the point of what he was</p> <p>9 trying to do was to be as gentle as possible without --</p> <p>10 basically the purpose is -- you know, when you say the outer</p> <p>11 layers mechanically removed, that means that when you look</p> <p>12 at these under a microscope, you'll see these layers of</p> <p>13 tissue, and you can gently remove them with a pair of</p> <p>14 tweezers. That's what I understand that he did.</p> <p>15 Q How thick is the layer of protein that's absorbed</p> <p>16 onto the mesh material?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 A Absorbed, or do you mean adherent protein? I'm</p> <p>19 not sure what you mean.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q I'll use your term, "adherent protein." How</p> <p>22 thick was that layer?</p> <p>23 A I'm not sure.</p> <p>24 Q On the order of a few microns?</p> <p>25 A I don't know.</p>
<p style="text-align: right;">Page 75</p> <p>1 detail in the paper that obviously satisfied the reviewers</p> <p>2 as to how those materials can be cleaned. He manually</p> <p>3 dissected it under a microscope with tweezers and a scalpel</p> <p>4 blade. I think that can be replicated. I don't see a</p> <p>5 problem with that.</p> <p>6 Q With all due respect, the only place I saw for a</p> <p>7 description of his methodology is on page 1 of Exhibit 2.</p> <p>8 A I was looking at page 5 in the paper where he</p> <p>9 says -- the X-ray photoelectron spectroscopy paragraph, he</p> <p>10 says, "Scraped fibers in which the outer layer was</p> <p>11 mechanically removed using tweezers and a scalpel blade</p> <p>12 under dissection microscope."</p> <p>13 Q Is that the extent of methodology that you're</p> <p>14 aware of?</p> <p>15 MR. JACKSON: Objection to form.</p> <p>16 A Yeah. I mean, I think it sounds pretty</p> <p>17 straightforward. He's been doing it for some time. The</p> <p>18 reviewers were fine with it. I mean, it's a mechanical</p> <p>19 dissection of tissue. People do that.</p> <p>20 Again, if you wanted all the details, if he has a</p> <p>21 protocol and all that, he would have to address that. I</p> <p>22 mean, I think for a paper, this is a reasonable description</p> <p>23 of the methodology. I'm looking on Exhibit 2 to see what's</p> <p>24 written there.</p> <p>25</p>	<p style="text-align: right;">Page 77</p> <p>1 Q Do you know how thick the blade is on a scalpel</p> <p>2 that he used, how it compares to the thickness of the</p> <p>3 proteins on the mesh?</p> <p>4 A I don't. Again, these types of detailed</p> <p>5 questions -- I don't know those types of details. Dr.</p> <p>6 Iakovlev did this, and I can't speculate on those types of</p> <p>7 things.</p> <p>8 Q Was there any consideration to testing the</p> <p>9 scraped mesh explant for other oxygen-containing molecules</p> <p>10 such as esters or cholesterol?</p> <p>11 A Well, I mean, again, we have to rely on what the</p> <p>12 XPS can tell us, and the XPS can tell us information about</p> <p>13 atoms that are there and the bonding. So esters are going</p> <p>14 to have carbonyl groups in them. It tells us about what</p> <p>15 molecules are there and the way that they're bound to each</p> <p>16 other.</p> <p>17 Q So you're looking at the data on the table that's</p> <p>18 on page 4, Exhibit No. 2?</p> <p>19 A I was referring back.</p> <p>20 Q Is there anything about the data on page 4 of</p> <p>21 Exhibit No. 2 that tells you that the oxygen that was found</p> <p>22 on the mesh explant was not an ester or a cholesterol?</p> <p>23 A I mean, it is an ester. I mean, I'm not sure</p> <p>24 what you mean by ester. I mean, it's an ester bond. I</p> <p>25 mean, it's -- well, it's not ester bond. It's a COO.</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 That carbonyl is present in an ester. If you 2 look at the degradation products -- I have to go back to 3 this. So I see what you're saying. I mean, an ester bond 4 would also have that carbonyl. It could also be, I think, 5 carboxylate. So it's not -- the XPS is just telling you 6 about those specific types of bonds. So, like in protein, 7 you could have esters, right. So it's -- I'm not being very 8 clear.</p> <p>9 The XPS tells you again about the type of bond. 10 You could have a carbonyl and an ester bond. It's also 11 present in the degradation of product from the 12 polypropylene.</p> <p>13 Q Right. And cholesterol may also appear in the 14 carbonyl group?</p> <p>15 A Maybe. I'd have to look at the structure.</p> <p>16 Q Why didn't you do a controlled experiment on a 17 pristine AMS mesh?</p> <p>18 A What do you mean by "controlled experiment"?</p> <p>19 Q Do the same testing XPS on a pristine AMS mesh.</p> <p>20 A I don't remember.</p> <p>21 Q Did you have that discussion?</p> <p>22 A I don't remember.</p> <p>23 Q Did you have pristine AMS mesh available to you?</p> <p>24 A I don't remember that either. Dr. Dunn had all 25 those materials. So I can't remember that one either.</p>	<p style="text-align: right;">Page 80</p> <p>1 BY MR. THOMAS:</p> <p>2 Q Doctor, would you turn to page 6 of Exhibit 1. 3 Page 6 of Exhibit 1 includes a paragraph called "Surface 4 degradation caused by SEM."</p> <p>5 A Yes.</p> <p>6 Q And who conducted this work?</p> <p>7 A Dr. Dunn.</p> <p>8 Q Do you know what kind of scanning electron 9 microscope was used?</p> <p>10 A That's hard to answer. We've replaced that 11 instrument at Vanderbilt. I can't remember where we were on 12 that when this work was done. Maybe -- well, let me see. 13 It might say in the -- we have several different SEMs. It's 14 Hitachi. We have a newer one now, I think.</p> <p>15 Q What is it about the Hitachi SEM that allows 16 measurement of peak depth?</p> <p>17 A Peak depth?</p> <p>18 MR. JACKSON: Objection to form.</p> <p>19 A Well, we used --</p> <p>20 BY MR. THOMAS:</p> <p>21 Q You have a number of measurements in this 22 paragraph going from 1 micron to 10 microns. How are you 23 able to measure that?</p> <p>24 A Well, I mean, as you can see, these are -- we're 25 saying greater than -- you know, these are not -- we didn't</p>
<p style="text-align: right;">Page 79</p> <p>1 Q What did you do to rule out contamination of the 2 explant?</p> <p>3 MR. JACKSON: Object to form.</p> <p>4 A Contamination?</p> <p>5 BY MR. THOMAS:</p> <p>6 Q Yes. Something from the environment that didn't 7 come from the mesh when it was implanted in the patient.</p> <p>8 A I mean, we use standard methodology for XPS 9 analysis, according to Dr. Rogers' papers. We removed the 10 protein mechanically the best we could. We tested, compared 11 the untreated to the treated -- and I'm sorry -- untreated 12 to the scraped. That's what we can do. I mean, we have no 13 evidence to believe there was significant contamination that 14 would alter the results.</p> <p>15 Q But you didn't take any steps to confirm that the 16 AMS explant had not been contaminated?</p> <p>17 MR. JACKSON: Objection to form.</p> <p>18 A I'm not really sure. Again, Dr. Rogers did that 19 work. It's difficult for me to -- I mean, we used existing 20 methods that we've used before to clean the mesh and to 21 analyze it. Dr. Rogers has published on XPS. I've 22 published with her on XPS. We use standard methods and 23 protocols for doing that work. There's no evidence to 24 suggest there was contamination. So that's kind of the way 25 the science is done.</p>	<p style="text-align: right;">Page 81</p> <p>1 do statistical analysis on these measurements.</p> <p>2 So the flaking, we have a scale bar on the SEM, 3 and you can see that those flakes and peeling features are 4 greater than 10 microns based on that scale bar. The depth 5 of the pits is a little bit more difficult. You could 6 estimate that to be in the range of a micron. We were just 7 trying to give some idea of the length scale of the 8 features.</p> <p>9 Q Is it fair to say the numbers there are 10 estimates?</p> <p>11 A I would say they're semiquantitative numbers 12 based on the images that are shown in the paper.</p> <p>13 Q If you go to page 9, there are scanning electron 14 microscopy images. Are there more images than what are 15 contained in the report?</p> <p>16 A So, I mean, it's the same for Figure 2. These 17 are representative images to give the reader some 18 perspective on what we saw. We -- I think we list them in 19 the report. I'm sorry. I keep saying -- this is a paper.</p> <p>20 Q I understand.</p> <p>21 A A published paper. I'm getting confused. So in 22 this paper we are -- so I basically -- we used low, medium, 23 high-magnification images. I think in the methods we 24 discussed how many images we took of each one, 5 to 15 25 images of each specimen. It just depended, it seems, on the</p>

21 (Pages 78 to 81)

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<p style="text-align: right;">Page 82</p> <p>1 specimen. So we have multiple images. These are</p> <p>2 representative ones to give some perspective on what we saw.</p> <p>3 Q And you would expect Dr. Dunn to have those</p> <p>4 images?</p> <p>5 A Yeah.</p> <p>6 Q Was he the one that provided the measurements and</p> <p>7 data that went into the paragraph I've just described on</p> <p>8 page 6?</p> <p>9 A That was probably me. I can't remember exactly.</p> <p>10 I probably did that.</p> <p>11 Q How did you do that? By looking at the scale</p> <p>12 bars?</p> <p>13 A Yeah. So you can look at the scale bar, and you</p> <p>14 can kind of draw a line on the feature. You can see that</p> <p>15 it's -- the purpose of like the greater than is to show that</p> <p>16 it is semiquantitative. We're giving some idea of a length</p> <p>17 scale. We didn't do specific measurements on those</p> <p>18 features. We just were trying to provide some perspective</p> <p>19 on the length scale.</p> <p>20 Q So other than the scale within the SEM itself,</p> <p>21 there was no effort to have a more precise measurement?</p> <p>22 MR. JACKSON: Objection to form.</p> <p>23 A You know, it's just difficult to measure that.</p> <p>24 The depth of a pit, you know, you could do profilometry, but</p> <p>25 it's not a flat surface. It's difficult to measure that</p>	<p style="text-align: right;">Page 84</p> <p>1 contractile forces from cells that infiltrate the mesh. So</p> <p>2 it's a combination of those forces and the chemical</p> <p>3 environment, chemical degradation that causes those cracks,</p> <p>4 and we believe that's why we didn't see it. That's what</p> <p>5 this discussion is saying.</p> <p>6 Q Was there anything about this experiment that</p> <p>7 prevented you from including some application mechanical</p> <p>8 force to try to replicate the transverse cracks?</p> <p>9 A Well, it can be done. It's just this was a first</p> <p>10 step. I mean, the first question we wanted to answer really</p> <p>11 is, can something oxidize? That was a question in this</p> <p>12 paper.</p> <p>13 I mean, to answer the cracking question, you</p> <p>14 would have to include some kind of stretching protocol, and</p> <p>15 that takes considerably more resources, time, effort and</p> <p>16 work. And we thought it made sense to start with the</p> <p>17 oxidation question since, you know, the degradation is a</p> <p>18 consequence of the oxidation. So that's why we started with</p> <p>19 that question, and that's why we didn't do mechanical forces</p> <p>20 in this study.</p> <p>21 Q Do you have plans to do any further study which</p> <p>22 would include the application of forces to try to replicate</p> <p>23 the transverse cracking?</p> <p>24 A I mean, these are research studies that are</p> <p>25 funded by external sponsors, so I can't really talk about</p>
<p style="text-align: right;">Page 83</p> <p>1 depth precisely. So we were doing the best we could from</p> <p>2 these images.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q And using the scale that's in there?</p> <p>5 A Yeah.</p> <p>6 Q Do you recognize in the paper that the flaking</p> <p>7 and pitting that you observed and report on page 9 in the</p> <p>8 SEMs is different from the transverse tracking that's been</p> <p>9 reported in other papers; correct?</p> <p>10 MR. JACKSON: Counsel, when you say "report,"</p> <p>11 we're talking about the published paper, right?</p> <p>12 BY MR. THOMAS:</p> <p>13 Q Dr. Guelcher, it's fair to understand that you</p> <p>14 reference in your paper the fact that the flaking and the</p> <p>15 pitting that you report and show in Figure 3 on page 9 of</p> <p>16 this paper is different from the transverse cracking that</p> <p>17 has been reported by others?</p> <p>18 A I think we addressed that in the discussion. So</p> <p>19 there's some -- yeah, so the last paragraph of discussion,</p> <p>20 you know, the point that we're making there is, this</p> <p>21 corrosion and stress cracking can happen when you have a</p> <p>22 combination of mechanical forces and chemical degradation,</p> <p>23 and in this experiment we only had chemical degradation.</p> <p>24 So we would not expect to see necessarily those</p> <p>25 transit cracks. It's the combination of forces, say</p>	<p style="text-align: right;">Page 85</p> <p>1 what we're doing.</p> <p>2 Q You can't answer the question?</p> <p>3 A No, I can't. It's research. I mean, I can't</p> <p>4 really talk about any research that we're doing. For this</p> <p>5 Wave 5 report on the line and these documents we've been</p> <p>6 talking about -- I just can't really talk about what we're</p> <p>7 doing right now. We're not relying on it.</p> <p>8 Q Do you have ongoing studies into the oxidation of</p> <p>9 polypropylene?</p> <p>10 A I just can't talk about it.</p> <p>11 Q Can you answer yes or no?</p> <p>12 A No, I can't answer yes or no. I can't really</p> <p>13 talk about what we're doing. It's an externally funded</p> <p>14 research project. It's confidential.</p> <p>15 Q Can you tell me who's funding the research</p> <p>16 project?</p> <p>17 A I mean, I never said there was a research</p> <p>18 project. I'm saying that, you know, our plans and ideas,</p> <p>19 these are all -- it's research. It's confidential.</p> <p>20 Q Okay. We may have to come back to that. How do</p> <p>21 you measure embrittlement?</p> <p>22 MR. JACKSON: Objection, form.</p> <p>23 A I think it's in my report, but I'll --</p> <p>24 embrittlement you could -- you could measure by mechanical</p> <p>25 testing, dynamic mechanical testing. It's a mechanical-type</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1 test.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q Have you done any embrittlement testing of any of</p> <p>4 the meshes that you've tested in Exhibit No. 1?</p> <p>5 A We have not. Again, it's a very technically</p> <p>6 challenging test to do, so we decided to start with things</p> <p>7 we could do using known and established methods.</p> <p>8 Embrittlement requires a certain kind of -- it</p> <p>9 would be more difficult to do, and we have to -- we haven't</p> <p>10 done it.</p> <p>11 MR. THOMAS: Let me take a break. Give me a few</p> <p>12 minutes. I may be close to wrapping up.</p> <p>13 MR. JACKSON: All right.</p> <p>14 (Recess was taken from 11:00 to 11:05.)</p> <p>15 (Exhibit 5 was marked for identification.)</p> <p>16 BY MR. THOMAS:</p> <p>17 Q I'm going to hand you now what's been marked as</p> <p>18 Deposition Exhibit Number 5, the Second Amended Notice of</p> <p>19 Deposition. This requested that you bring with you to the</p> <p>20 deposition a number of things. I've received the filing by</p> <p>21 your counsel about objections. I've also received some</p> <p>22 billing information, a copy of the 2017 published article,</p> <p>23 which is Exhibit 1, supplemental data which is Exhibit</p> <p>24 Number 2.</p> <p>25 There is a deposition request that you also</p>	<p style="text-align: right;">Page 88</p> <p>1 A Maybe a year ago. No, six months. Within a</p> <p>2 year.</p> <p>3 Q What does she do for FDA?</p> <p>4 A She is a reviewer of medical device applications.</p> <p>5 Q Where does she work in Maryland?</p> <p>6 A She works at FDA.</p> <p>7 Q I understand that, but Maryland is a big state.</p> <p>8 I don't mean to be flip, but I'm just trying to find out</p> <p>9 which city.</p> <p>10 A I don't know. I don't know where exactly she</p> <p>11 lives.</p> <p>12 Q Is it closer to Washington D.C. or closer to</p> <p>13 Baltimore? Do you have any idea?</p> <p>14 A Probably D.C.</p> <p>15 Q And Dr. Rogers still work at Vanderbilt?</p> <p>16 A Yes.</p> <p>17 Q Dr. Dunn still at Vanderbilt?</p> <p>18 A Yes.</p> <p>19 Q Were you the person who was responsible for</p> <p>20 organizing the study?</p> <p>21 MR. JACKSON: Objection, form.</p> <p>22 A I would say that Dr. Dunn and I did that</p> <p>23 together. We thought about what question we want to ask,</p> <p>24 how we could design the study, then we maybe talked to Dr.</p> <p>25 Iakovlev about explants.</p>
<p style="text-align: right;">Page 87</p> <p>1 produce all of the underlying data for the Exhibit Number 1</p> <p>2 and Exhibit No. 2, and I believe we've covered that today in</p> <p>3 your deposition, that is, to the extent that that data is</p> <p>4 available, it's in the custody or control of the people who</p> <p>5 conducted the work and not in your current possession. Is</p> <p>6 that fair?</p> <p>7 A That's right.</p> <p>8 Q And you did not ask them to give that information</p> <p>9 to you for purposes of this deposition; correct?</p> <p>10 A I did not because that's just not how things are</p> <p>11 done. I think if you want somebody's data, you have to ask</p> <p>12 them directly.</p> <p>13 Q Have you had any -- as corresponding author, have</p> <p>14 you had any inquiries about the work that went into the</p> <p>15 Talley study?</p> <p>16 A I've had requests for the paper, and I've sent</p> <p>17 that to people, but I haven't had any detailed questions</p> <p>18 about it.</p> <p>19 Q Other than producing the paper, have you</p> <p>20 discussed with anybody else your methodology or the results</p> <p>21 that you've reached?</p> <p>22 A Not that I can remember.</p> <p>23 Q Where does Ms. Talley live now, Dr. Talley?</p> <p>24 A She lives in Maryland. She works for FDA.</p> <p>25 Q When did she take her job with FDA?</p>	<p style="text-align: right;">Page 89</p> <p>1 So probably mostly it was probably Dr. Dunn and</p> <p>2 me planning the study.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q On page 13 of Exhibit No. 1 under the disclosure</p> <p>5 statement and funding it says, "Russell F. Dunn is the owner</p> <p>6 of Polymer Chemical Technologies, which sponsored the work."</p> <p>7 A Yes.</p> <p>8 Q Are there other employees of Polymer Chemical</p> <p>9 Technologies, to your knowledge?</p> <p>10 A I don't know at the moment. You would have to</p> <p>11 ask Dr. Dunn about that. I don't know if he has any</p> <p>12 employees right now.</p> <p>13 Q There's been a time when that was just him?</p> <p>14 A I mean, his business has changed over the years.</p> <p>15 Sometimes he's had employees, sometimes not. So I don't</p> <p>16 know right now. When this work was done, I don't know.</p> <p>17 Q The work was supported by Polymer and Chemical</p> <p>18 Technologies, LLC, Grant Number VU1349. Did you prepare a</p> <p>19 grant request to Polymer and Chemical Technologies for this</p> <p>20 work?</p> <p>21 A No.</p> <p>22 Q What is -- is VU Vanderbilt University?</p> <p>23 A Yes.</p> <p>24 Q So how does Vanderbilt University 1349 obtain a</p> <p>25 grant from Polymer and Chemical Technologies?</p>

23 (Pages 86 to 89)

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<p>1 A I mean, any company can enter into an agreement</p> <p>2 called a sponsored research agreement. I've done this</p> <p>3 before with other companies. Any company can enter into an</p> <p>4 agreement with the University to sponsor research. It's a</p> <p>5 standard thing.</p> <p>6 Q Is it your suggestion that Vanderbilt is a</p> <p>7 sponsor of this research?</p> <p>8 A No.</p> <p>9 Q Okay.</p> <p>10 A It's a sponsored research agreement so an</p> <p>11 external sponsor -- could be a foundation, could be federal</p> <p>12 government, could be a company -- enters into a contractual</p> <p>13 relationship with Vanderbilt University where they agree to</p> <p>14 sponsor research at Vanderbilt. So they pay for the</p> <p>15 research, but the research is done at Vanderbilt. So</p> <p>16 there's a contract that regulates that.</p> <p>17 Q So there's a contract for this study between</p> <p>18 Polymer Chemical Technologies and Vanderbilt University?</p> <p>19 A I don't know if it's for the study. Again, you'd</p> <p>20 have to ask Russell about the details of how his company --</p> <p>21 his relationship between his company and Vanderbilt is</p> <p>22 something I can't really address.</p> <p>23 What I can tell you is that when this says Grant</p> <p>24 Number VU1349, that means that there's some sponsored</p> <p>25 research agreement between Polymer Chemical Technologies and</p>	<p>1 He's the owner, as it says here. I don't -- I don't know --</p> <p>2 I mean, I can't answer these questions. You're asking</p> <p>3 questions about how Polymer Chemical Technologies, who I</p> <p>4 have no relationship with, is doing business. I can't</p> <p>5 answer that.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q I asked you whether you've been party to any</p> <p>8 conversations where it was determined that lawyers in this</p> <p>9 litigation would fund Polymer Chemical Technologies, LLC to</p> <p>10 supply the grant for the work that's done in Exhibits 1 and</p> <p>11 2.</p> <p>12 MR. JACKSON: I think to the extent you're asking</p> <p>13 about conversations between attorneys and the witness,</p> <p>14 that's privileged information.</p> <p>15 MR. THOMAS: Are you directing him not to answer?</p> <p>16 MR. JACKSON: I think he's already answered the</p> <p>17 question.</p> <p>18 MR. THOMAS: Are you directing him not to answer?</p> <p>19 MR. JACKSON: No, I'm not, because I think he's</p> <p>20 already answered the question.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q The question is, have you been party to any</p> <p>23 conversations with lawyers where it's been discussed lawyers</p> <p>24 funding Polymer Chemical Technologies, LLC grant for the</p> <p>25 work that's done in Exhibits Number 1 and 2?</p>
Page 91	Page 93
<p>1 Vanderbilt. The scope of that agreement, I don't know the</p> <p>2 details. That's all I can say from that sentence.</p> <p>3 Q How much was the grant?</p> <p>4 A I don't know.</p> <p>5 Q Was there any other financial support to the work</p> <p>6 in Exhibits Number 1 and 2 beyond what was supplied by</p> <p>7 Polymer and Chemical Technologies, LLC?</p> <p>8 A No.</p> <p>9 Q Do you know whether Polymer and Chemical</p> <p>10 Technologies, LLC obtained money from any other source to</p> <p>11 fund this research?</p> <p>12 A I don't -- again, I don't know the details of how</p> <p>13 the company contracted with Vanderbilt. I don't know those</p> <p>14 details. I can just -- from the way that's written, I can</p> <p>15 infer that there's a contract.</p> <p>16 Q If you had any conversations with any lawyers</p> <p>17 about obtaining money to be supplied to Polymer and Chemical</p> <p>18 Technologies, LLC that would be used as a grant to fund the</p> <p>19 work in Exhibits Number 1 and 2?</p> <p>20 MR. JACKSON: This is clearly privileged</p> <p>21 information you're asking him about.</p> <p>22 MR. THOMAS: Oh, I don't think so.</p> <p>23 MR. JACKSON: No?</p> <p>24 A Again, I have no relationship with Polymer</p> <p>25 Chemical Technologies. This is Russell Dunn's company.</p>	<p>1 A I mean, I can't really discuss all the</p> <p>2 conversations we have with counsel. I mean, I --</p> <p>3 Q He hasn't instructed you not to answer. He's</p> <p>4 permitted you to answer the question.</p> <p>5 MR. JACKSON: I'm instructing him not to answer</p> <p>6 to the extent it calls for any communications between</p> <p>7 himself and attorneys.</p> <p>8 MR. THOMAS: That's fine. We'll fight that one.</p> <p>9 A Let me think about this for a second, all right.</p> <p>10 I'm trying not to --</p> <p>11 MR. JACKSON: I think he's already given you an</p> <p>12 answer to the question.</p> <p>13 MR. THOMAS: I'm not going to argue with you.</p> <p>14 A Let's just -- can we just go with what's written</p> <p>15 here? Can we do that?</p> <p>16 BY MR. THOMAS:</p> <p>17 Q I can read it as well as you can. I'm just</p> <p>18 trying to figure out what else is involved that's not here.</p> <p>19 A Well, what did we disclose? Russell and I --</p> <p>20 Dr. Dunn and I have disclosed these matters to the</p> <p>21 University, and we have -- we have an annual disclosure, and</p> <p>22 all of this has been disclosed.</p> <p>23 In the paper we disclose several things. We say</p> <p>24 that Russell Dunn is the owner of Polymer Chemical</p> <p>25 Technologies. Polymer Chemical Technologies sponsored the</p>

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Page 94	Page 96
1 work.	1 ACKNOWLEDGMENT OF DEPONENT
2 I mean, that means that that company, through	2
3 this grant, VU1349, gave money to Vanderbilt, and this work	3 I, SCOTT GUELCHER, Ph.D., do hereby certify that
4 was done within that context.	4 I have read the foregoing pages and that the same is a
5 I don't know the details of that contract. I	5 correct transcription of the answers given by me to the
6 don't know if it funded other work. All I know is, there's	6 questions therein propounded, except for the corrections or
7 a contract between PCT and the University, and this work was	7 changes in form or substance, if any, noted in the attached
8 done within the context of that contract. Dr. Iakovlev and	8 Errata Sheet.
9 I disclosed the fact that we provided opinions in these	9
10 cases. So this is what we disclosed.	10
11 To go into like conversations with attorneys	11
12 about paying for experiments, I can't talk about that.	12
13 That's -- this is, you know, privileged information with	13 SCOTT GUELCHER, Ph.D. Date
14 attorneys.	14
15 Q Okay.	15 Subscribed and sworn to before me this
16 A We did not say that they funded the study. This	16 ___ day of ___, 20__.
17 study was funded by the company. But I can't go any further	17 My commission expires: _____
18 than that. I can't --	18
19 MR. THOMAS: I keep forgetting I've got more time	19
20 than I thought I did. I'm on eastern time. Doctor,	20 Notary Public
21 I'm going to quit. Thank you very much for your time.	21
22 THE WITNESS: Thank you.	22
23 MR. THOMAS: Have a safe trip to Australia.	23
24 MR. JACKSON: I have no questions.	24
25 (Deposition concluded at 11:17.)	25

Page 95	Page 97
1 CERTIFICATE	1
2 I, Gina Hawkins, Licensed Court Reporter for the	2 ERRATA
3 State of Tennessee, do certify that the above deposition was	3
4 reported by me and that the foregoing transcript is a true	4 PAGE LINE CHANGE/REASON
5 and accurate record to the best of my knowledge, skills, and	5
6 ability.	6
7 I further certify that I am not an employee of	7
8 counsel or any of the parties, nor a relative or employee of	8
9 any attorney or counsel connected with the action, nor	9
10 financially interested in the action.	10
11 I further certify that I am duly licensed by the	11
12 Tennessee Board of Court Reporting as a Licensed Court	12
13 Reporter as evidenced by the LCR number following my name	13
14 below.	14
15 Subscribed and sworn to before me when taken this	15
16 17th day of August, 2017.	16
17	17
18	18
19 GINA HAWKINS, LCR #780	19
20 Expiration Date: 6/30/2019	20
21	21
22	22
23	23
24	24
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25 (Pages 94 to 97)

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EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

	X	
	:	
IN RE: ETHICON, INC.	:	MDL No. 2:12-md-02327
PELVIC REPAIR SYSTEM	:	
PRODUCTS LIABILITY LITIGATION	:	DATE: September 26, 2017
	X	

TRANSCRIPT OF MOTIONS HEARING HELD
BEFORE THE HONORABLE CHERYL A. EIFERT
UNITED STATES MAGISTRATE JUDGE
HUNTINGTON, WEST VIRGINIA

APPEARANCES:

(All counsel appearing by telephone.)

For the Plaintiffs:	Edward A. Wallace Timothy E. Jackson Wexler Wallace Suite 3300 55 West Monroe Street Chicago, IL 60603 D. Renee Baggett Aylstock Witkin Kreis & Overholtz Suite 200 17 East Main Street Pensacola, FL 32502
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For the Defendant:	David B. Thomas Thomas Combs & Spann, PLLC P. O. Box 3824 Charleston, WV 25338-3824
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Court Reporter:	Kimberly Kaufman, RMR, CRR
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Proceedings recorded by mechanical stenography;
transcript produced by computer.

1 PROCEEDINGS had before The Honorable Cheryl A. Eifert,
2 Magistrate Judge, United States District Court, Southern
3 District of West Virginia, in Huntington, West Virginia, on
4 September 26, 2017, at 9:30 a.m., as follows:

5 MS. TATMAN: We are here in the Ethicon MDL case
6 2:12-md-02327. This is concerning defendant's motion to
7 compel discovery or in the alternative to exclude certain
8 opinion testimony. That's ECF No. 4582.

9 May I please have plaintiff's counsel?

10 MR. WALLACE: Yes, this is Ed Wallace for the
11 plaintiffs. And I also believe Tim Jackson is on the line.

12 MR. JACKSON: Yes, this is Tim Jackson. I'm on
13 the line.

14 MS. BAGGETT: Renee Baggett is also on the line.

15 MS. TATMAN: Thank you. Counsel for Ethicon,
16 please.

17 MR. THOMAS: David Thomas.

18 MS. TATMAN: All right. If that's everyone, I'll
19 remind you, when you are speaking, to please identify
20 yourself for the sake of transcript. And one moment for
21 Judge Eifert, please.

22 THE COURT: Good morning. All right. We are here
23 today on defendant's motion to compel discovery or in the
24 alternative to exclude certain opinion testimony. I have
25 read all of the submissions.

1 Let me ask a couple of questions. I saw where there
2 was a supplement that was provided by the plaintiffs to the
3 defendant, but am I correct in understanding that that
4 supplement does not contain all of the raw data?

5 MR. THOMAS: This is David Thomas, Your Honor.
6 That's correct. The supplement was published data that was
7 a summary of that data. We do not have the raw data that
8 was requested.

9 THE COURT: All right. Let me ask you, Mr.
10 Thomas, have you made any effort to subpoena that
11 information?

12 MR. THOMAS: If we're not successful here, we will
13 go after the co-authors to subpoena the information. We
14 have not done that pending the outcome of this issue.

15 THE COURT: Okay. So here's where I come down on
16 this. As far as the standard that you would apply as to
17 whether or not this information is within the control of the
18 doctor, I don't think the standard is really set in stone.
19 I did a review yesterday. It's a bit of a flexible standard
20 depending on where you are in the country and what circuit
21 you're in, and even within the Fourth Circuit there's some
22 disagreement as to what the standard is.

23 Some courts believe that there has to be a legal right
24 to the materials before you have control of them or there
25 has to be some close relationship between the person who

1 holds the information and the party that's asked to produce
2 it: For example, subsidiaries and parent corporations, that
3 sort of thing.

4 Then there's a series of cases, especially in this
5 district and in this -- well, mainly this district -- not
6 just this district, Maryland as well -- where they say as
7 long as you have the practical ability to obtain the data or
8 the information, then you do have control over it. So there
9 is this range and this -- I think it's not entirely clear
10 what would be the proper standard to use, but honestly I
11 don't know that that matters a whole lot in the end result
12 because the fact is that the doctor did testify that he is
13 able to get this data.

14 And so I don't think we should make a mountain out of a
15 molehill as far as which standard to apply. I think
16 probably I'm leaning more toward the practical ability to
17 obtain the data. When I say that, I don't think that's an
18 incorrect standard to apply. I don't think it's universal,
19 but in this case it makes sense to me. And I think it
20 really makes sense because if you look at Rule 26(a)(2)(B),
21 the report provided by the expert is supposed to in some way
22 contain or supply the facts and data considered by the
23 expert in reaching his or her opinion.

24 Dr. Sculpture (phonetic) also testified that he did
25 review and consider the raw data. So from that standpoint,

1 I think that the defendants are entitled to the raw data. I
2 think the defendants are also entitled to the protocol and
3 photographs that the one physician might have who did the
4 separation of the fibers, any images, any information about
5 the specimen. I think all of that is data. It's factual
6 information that ought to be supplied to the defendant so
7 that they have an opportunity to undermine the credibility
8 and reliability of this particular paper.

9 Having said that, I don't think I saw anywhere in the
10 deposition where the doctor mentioned that he relied on
11 communications with co-authors or particular review boards
12 or that he relied on investigator brochures. I don't even
13 know whether this is the kind of situation where there would
14 be adverse events for informed consent. So I don't think
15 the defendants are entitled to those various categories of
16 information.

17 So I am going to order the plaintiffs to provide to
18 Ethicon -- or defendant if there's more than just Ethicon --
19 the raw data, the materials -- the information regarding
20 specimens, if that exists, the protocols, any photographs,
21 images that have to do with the fibers that were separated
22 and used and examined, so that kind of factual information.

23 I'm not going to require the plaintiffs to produce
24 informed consents, adverse events, investigator brochures.
25 I think they've already given defendants the submissions and

1 I'm not going to make the plaintiffs produce communications
2 with co-authors, et cetera.

3 Now, that, to me, takes care of the first issue, and
4 I'll let either side say whatever they might want to say on
5 the record about my ruling before I go on to the second
6 question, which is this supplemental deposition.

7 Who would like to go first? Mr. Thomas, it's your
8 motion. Is there something you would like to add or say on
9 the record?

10 MR. THOMAS: No, Your Honor, nothing further.
11 Thank you.

12 MR. WALLACE: Your Honor, this is Ed Wallace,
13 plaintiff's counsel, Your Honor, and Tim Jackson, who had
14 most of the dealings with Mr. Thomas, is also on the line to
15 address any of the communications between them, but given
16 Your Honor's ruling I have a few practical sort of
17 questions/suggestions that we're probably going to need some
18 guidance on.

19 One of those is the reality of what we do. In other
20 words, there are, I believe, multiple co-authors, all of
21 whom may or may not have information who will be required to
22 spend a lot of time and effort, and including us spending a
23 lot of time and effort to -- for example, I don't know if I
24 now have to fly to Toronto to determine whether or not --
25 you know, what those specimens -- where they're kept now, et

1 cetera.

2 As you know this much of the peer review process so
3 once the article was written and approved and published, I'm
4 not sure what those co-authors did with any of that
5 underlying data. And much like, for example, defendant's
6 expert who recently, I believe, was published, the question
7 I have beyond that is what is good for the goose is good for
8 the gander. We'd love to have all the underlying data for
9 every article that's ever been published that's relied on by
10 an expert and I whether or not we're opening up a can of
11 worms here in that regard.

12 I was just wondering if Your Honor could outline some
13 of the limits of what this ruling is really is so we don't
14 get into that because I'd hate to see that start happening
15 every other week and so forth. Those are really my what I
16 call two practical concerns.

17 THE COURT: Well, let me say this: What Rule 26
18 provides is that if the expert considered that data, then
19 that -- those facts and data need to in some way be
20 disclosed to the other side. Obviously you're always going
21 to have proportionality concerns, there's going to be
22 burdensome arguments and things of that nature. I think
23 clearly if someone no longer has the data, then there's
24 nothing to produce.

25 I think in this case, because he testified that he

1 relied on this raw data -- and I looked for that very
2 carefully because -- I think it's at page 16 of his
3 transcript. I looked for that very carefully because when I
4 was reading through some of it, it sounded to me like he
5 really didn't review or rely on or consider the raw data,
6 that he had these various other individuals that were the
7 principal investigators -- and I think there were only
8 really three other people other than his students that I
9 understood had any of this information. That being Barry
10 Rodgers and -- I can't pronounce that person's name, but the
11 one who actually separated the fibers.

12 My understanding was there were three other people and
13 it looked at first as though he was going to say I really
14 didn't do that, I just relied on this, relied on that, but
15 then at some point he does say at page 16 that he did look
16 at the raw data and he did consider it. Once he said that,
17 I think now it's up for grabs because of Rule 26.

18 As far as these other arguments go, none of those
19 arguments were made in response to this motion so I'm not in
20 a position to say whether this was too burdensome or whether
21 it's disproportional. So all of these things have to be
22 taken sort of case-by-case.

23 I understand your concerned about opening up this whole
24 issue about always producing the raw data. I would think
25 for the most part people aren't going to want the raw data

1 because it's not going to add anything and it's just going
2 to be additional information that you don't really need to
3 have. Obviously you don't have to produce raw data for
4 articles that were not written by the expert. That's going
5 to be impossible to do and that's not something that the
6 expert would have control over anyway.

7 But in this case, this is what the request was. I see
8 there's a basis for it. He can get the data. So I think
9 you need to move on that and see what's out there and how
10 long it's going to take to collect it.

11 It didn't sound to me like it was going to be all that
12 hard from what I read. It sounded like most of it was
13 computerized and it was just stored somewhere. So it may be
14 nothing more than downloading it on a thumb drive and
15 sending it to Mr. Thomas, but it's hard for me to tell
16 because those issues weren't really raised.

17 MR. WALLACE: Your Honor, along those lines I
18 guess what I'm hearing -- I understand, as you point out,
19 this is sort of a case-by-case issue. What I'm hearing is
20 we will, pursuant to your ruling, act promptly, like today,
21 to uncover exactly where that's at, what we can get and
22 exactly what he relied on and then we will confer with Mr.
23 Thomas as soon as possible.

24 If there are issues, for example, of the things that do
25 come up in discovery like proportionality or burden or those

1 sorts of things, we're obviously not going to waste your
2 time with what I'll call the trivial stuff, but if there's
3 something very serious that comes up, we may need to address
4 that with the court.

5 I'm not going to telegraphing anything because I've had
6 pretty good dealings with Mr. Thomas, but my concern is I
7 don't want to turn this in to a 90-day search for everything
8 under the sun. I want to get this done. I want to get --
9 your ruling obviously is what it is and it's -- I construe
10 it narrowly enough that we can get this done pretty quickly.

11 THE COURT: Let me say, Mr. Wallace, that's the
12 way I'm thinking as well. The impression that I got was
13 that this would not be that hard to collect and that hard to
14 get together. I might ask Mr. Thomas, too, to maybe discuss
15 with his experts what raw data they really think would be
16 important to impeach the article. I don't know that
17 everything -- all of the raw data is going to be that
18 important. Maybe it is. I don't know, but I would say that
19 there ought to be some effort on the defendant's side to
20 narrow what it is that you really need and not just collect
21 a bunch of extraneous information for no other reason than
22 you feel like you have to have it.

23 I would think your experts would have some idea of
24 where there might be weaknesses in the study itself and
25 where the raw data might truly make a difference in the

1 opinions expressed in the article. I would ask you to look
2 at that and try to work together.

3 If it turns out that this is becoming a huge problem,
4 don't wait 30 days to come back. Come back in two weeks or
5 however long -- because I expect you both are going to get
6 right on it. Aren't you way done with discovery now?

7 MR. WALLACE: Well, I sure hope so.

8 THE COURT: I thought the deadline had expired a
9 while ago so I don't see this as being something that's
10 going to take 90 days, but 60 days or even 30 days. I'm
11 thinking this should be fairly easy to gather because it
12 sounded like it was all computer-generated data to me, but
13 if that's not the case --

14 MR. THOMAS: This is David Thomas. I want to just
15 respond to that briefly. I'll certainly work with Mr.
16 Wallace. We always have worked well together on these
17 issues. This has been a two-way street. We've been through
18 this whole process with one of our experts who published a
19 study and we produced all the underlying data. And, in
20 fact, even his assistants who worked on the testing were
21 deposed. This is something we've been through before on the
22 defense side and I'd like to think that Mr. Wallace and I
23 will be able to work through this easily. If not, we'll be
24 back, but Mr. Wallace and I get along pretty well and I
25 think we'll be able to work through this.

1 THE COURT: Very good. The second issue is the
2 deposition. Here is how I am ruling on that. First of all,
3 the discovery deadline's over so I don't have authority to
4 extend it to allow you to take a supplemental deposition. I
5 think Judge Goodwin recently entered an order letting
6 everybody know that he doesn't want you stipulating around
7 the deadlines. So obviously I don't have that authority
8 anyway.

9 But let me add this, even if I did have the authority,
10 I would not grant that motion for a supplemental deposition
11 and here's the reason why: He did consider the raw data,
12 but it's very clear to me in this deposition that he really
13 relied on these other people to do the work -- the
14 nitty-gritty work of what area they were the principal
15 investigator on. I don't think he would really be a
16 valuable witness in talking about the ins and outs of the
17 raw data.

18 He obviously looked at it, considered it, but he didn't
19 perform any of those tests. He didn't set the protocols.
20 He didn't come up with the figures. He didn't make the
21 calculation.

22 To me that would just be a waste of time spent on
23 deposing him about things that he doesn't really have
24 personal knowledge of, so for that reason I would deny that
25 anyway, but, of course, the main reason is that discovery is

1 over at this point.

2 Does anybody want to say anything to that?

3 MR. THOMAS: Not at this point, Your Honor. David
4 Thomas.

5 MR. WALLACE: All right. No, Your Honor. Thank
6 you. Ed Wallace speaking.

7 THE COURT: All right. So I think that takes care
8 of everything. I'll do my usual very short order saying we
9 had a hearing, we discussed it and I'm ruling in accordance
10 with what was said during the hearing. All right?

11 MR. THOMAS: Thank you, Your Honor.

12 MR. WALLACE: Thank you, Your Honor.

13 THE COURT: Thank you.

14

15 (Proceedings concluded at 9:49 a.m., September 26, 2017.)

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1 CERTIFICATION:

2 I, Kimberly Kaufman, Official Court Reporter, certify
3 that the foregoing is a correct transcript from the record
4 of proceedings in the matter of In Re: Ethicon, Inc., Pelvic
5 Repair System Products Liability Litigation, MDL No.
6 2:12-md-02327, as reported on September 26, 2017.

7
8 s/Kimberly Kaufman, RMR, CRROctober 2, 2017

9 Kimberly Kaufman, RMR, CRR

DATE

EXHIBIT F

-----Original Message-----

From: David Thomas

Sent: Monday, October 2, 2017 9:52 AM

To: Edward Wallace <EAW@wexlerwallace.com>

Cc: Steve Brody <sbrody@omm.com>; Christy Jones <Christy.Jones@butlersnow.com>; David Thomas <DThomas@tcspllc.com>; Phil Combs <PCombs@tcspllc.com>; Robyn Davis <RDavis@tcspllc.com>

Subject: Huskey

Ed--as you may know, the Supreme Court denied the Huskey cert petition today. I am out of the office but will be in touch shortly concerning payment of the judgment.

Also, we need to discuss the production of documents ordered by Magistrate Eifert.

Please advise of your availability this week. Thanks.

David

EXHIBIT G

From: [David Thomas](#)
To: [Aaron Arthur](#)
Subject: FW: Kaiser v. Ethicon
Date: Thursday, October 26, 2017 8:25:40 AM

From: Edward Wallace [mailto:EAW@wexlerwallace.com]
Sent: Thursday, October 12, 2017 2:15 PM
To: David Thomas <DThomas@tcspllc.com>
Cc: Christy D. Jones (Christy.Jones@butlersnow.com) <Christy.Jones@butlersnow.com>
Subject: RE: Kaiser v. Ethicon

Let me get back to you tomorrow. By the way, you should want me in the Kaiser case – I am the reasonable one!

From: David Thomas [<mailto:DThomas@tcspllc.com>]
Sent: Thursday, October 12, 2017 1:12 PM
To: Edward Wallace <EAW@wexlerwallace.com>
Cc: Christy D. Jones (Christy.Jones@butlersnow.com) <Christy.Jones@butlersnow.com>; David Thomas <DThomas@tcspllc.com>
Subject: Kaiser v. Ethicon

Ed—please let me know when you are available to talk about (1) your progress in producing the Talley information ordered by Judge Eifert and (2) what I understand to be your participation in the Kaiser trial. We understand that Dr. Guelcher is scheduled to testify next month; we need the information ordered by Judge Eifert in advance of that trial. Also, I was advised by Tom Plouff that you plan to participate in the Kaiser trial. If you have not seen, please know that Ethicon believes that your settlement with Motley Rice precludes that participation.

E. Present Intentions

1. The Participating Law Firms agree that they will not participate in any trials or depositions in cases against Ethicon involving Ethicon Pelvic Mesh Products except for trials or depositions that involve: (1) plaintiffs who were implanted with currently marketed Ethicon Pelvic Mesh Products who have not undergone a Revision Surgery as of the Effective Date that are identified on Exhibit J to this Agreement (recognizing that such cases may be subject to docket control orders entered in the jurisdictions where the cases are pending); (2) the Participating Law Firm's future clients, if any, so long as the engagement of such clients is consistent with the Participating Law Firm's present intentions as expressed in paragraph V.E.2; or (3) any Plaintiff identified on Exhibit A or F to this Agreement that rejects the settlement. The parties agree that it shall not be a violation of this Agreement for Lead Law Firm (not Participating Law Firms) to provide support or assistance including participation in depositions and court proceedings

in connection with its role in MDL proceedings or State Court appointed leadership positions on issues that are common to the MDL, Consolidated proceedings, or Lead Law Firm's clients.

Please let me know when you are available to discuss. Thanks.

David B. Thomas

Thomas, Combs & Spann PLLC
300 Summers Street, Suite 1380
Charleston, WV 25301

Telephone (main)—304-414-1800
Telephone (direct)—304-414-1807

EXHIBIT H

From: [David Thomas](#)
To: [Edward Wallace](#)
Cc: [Christy D. Jones \(Christy.Jones@butlersnow.com\)](#); [Chad Hutchinson \(Chad.Hutchinson@butlersnow.com\)](#); [Aaron Arthur](#); [David Thomas](#)
Subject: RE: Kaiser v. Ethicon
Date: Wednesday, October 18, 2017 3:20:31 PM

Ed—need an answer here, please. When can we expect the Guelcher/Talley data? Thank you.

David

From: Edward Wallace [mailto:EAW@wexlerwallace.com]
Sent: Thursday, October 12, 2017 2:15 PM
To: David Thomas <DThomas@tcspllc.com>
Cc: Christy D. Jones (Christy.Jones@butlersnow.com) <Christy.Jones@butlersnow.com>
Subject: RE: Kaiser v. Ethicon

Let me get back to you tomorrow. By the way, you should want me in the Kaiser case – I am the reasonable one!

From: David Thomas [mailto:DThomas@tcspllc.com]
Sent: Thursday, October 12, 2017 1:12 PM
To: Edward Wallace <EAW@wexlerwallace.com>
Cc: Christy D. Jones ([Christy.Jones@butlersnow.com](#)) <[Christy.Jones@butlersnow.com](#)>; David Thomas <[DThomas@tcspllc.com](#)>
Subject: Kaiser v. Ethicon

Ed—please let me know when you are available to talk about (1) your progress in producing the Talley information ordered by Judge Eifert and (2) what I understand to be your participation in the Kaiser trial. We understand that Dr. Guelcher is scheduled to testify next month; we need the information ordered by Judge Eifert in advance of that trial. Also, I was advised by Tom Plouff that you plan to participate in the Kaiser trial. If you have not seen, please know that Ethicon believes that your settlement with Motley Rice precludes that participation.

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agree that it shall not be a violation of this Agreement for Lead Law Firm (not Participating Law Firms) to provide support or assistance including participation in depositions and court proceedings in connection with its role in MDL proceedings or State Court appointed leadership positions on issues that are common to the MDL, Consolidated proceedings, or Lead Law Firm's clients.

Please let me know when you are available to discuss. Thanks.

David B. Thomas

Thomas, Combs & Spann PLLC
300 Summers Street, Suite 1380
Charleston, WV 25301

Telephone (main)—304-414-1800
Telephone (direct)—304-414-1807

EXHIBIT I

From: Timothy Jackson [<mailto:TEJ@wexlerwallace.com>]

Sent: Friday, October 20, 2017 5:10 PM

To: David Thomas <DThomas@tcspllc.com>

Cc: Edward Wallace <EAW@wexlerwallace.com>

Subject: Raw Data from 2017 Talley et al Article

Hi David,

We received the attached raw FTIR data associated with the 2017 Talley et al article from Dr. Guelcher. We will follow up on this with you Tuesday.

Thanks,

Tim

Timothy E. Jackson

WEXLER WALLACE LLP

55 West Monroe, Suite 3300 // Chicago, IL 60603

T 312.346.2222 // F 312.346.0022 // Direct T 312.589.6278

www.wexlerwallace.com

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EXHIBIT J

From: [Aaron Arthur](#)
To: [Robyn Davis](#)
Subject: FW: Raw Data from 2017 Talley et al Article
Date: Monday, November 6, 2017 11:44:27 AM

From: Timothy Jackson [mailto:TEJ@wexlerwallace.com]
Sent: Thursday, October 26, 2017 3:34 PM
To: David Thomas
Cc: Aaron Arthur; Edward Wallace
Subject: RE: Raw Data from 2017 Talley et al Article

David,

Can we set up a call tomorrow morning to discuss? We can be available anytime between 9 and 11 am central. Let us know what works.

Tim

From: David Thomas [mailto:DThomas@tcspllc.com]
Sent: Thursday, October 26, 2017 1:15 PM
To: Edward Wallace
Cc: Timothy Jackson; Aaron Arthur
Subject: RE: Raw Data from 2017 Talley et al Article

Ed—I have attached the order and the transcript. I direct your attention to your comments re timing of production on pages 9-10 and the order which specifies the information the court ordered to be produced. Ethicon suggests that plaintiffs have not complied with the order or the commitment to timely produce, leaving no option but to file a motion. I am available tomorrow to discuss.

David

From: Edward Wallace [mailto:EAW@wexlerwallace.com]
Sent: Thursday, October 26, 2017 1:56 PM
To: David Thomas <DThomas@tcspllc.com>
Cc: Timothy Jackson <TEJ@wexlerwallace.com>; Aaron Arthur <AArthur@tcspllc.com>
Subject: Re: Raw Data from 2017 Talley et al Article

Dave - why don't we talk by phone first. You have jumped the gun - if you are not satisfied with what you have you might try reaching out.

Edward A. Wallace

On Oct 26, 2017, at 1:48 PM, David Thomas <DThomas@tcspllc.com> wrote:

Gentlemen—I have heard nothing further. Obviously, there is quite a bit not

produced. We will be filing a motion immediately given the passage of time and lack of compliance with the order of the court.

David

From: Timothy Jackson [<mailto:TEJ@wexlerwallace.com>]

Sent: Friday, October 20, 2017 5:10 PM

To: David Thomas <DThomas@tcspllc.com>

Cc: Edward Wallace <EAW@wexlerwallace.com>

Subject: Raw Data from 2017 Talley et al Article

Hi David,

We received the attached raw FTIR data associated with the 2017 Talley et al article from Dr. Guelcher. We will follow up on this with you Tuesday.

Thanks,
Tim

Timothy E. Jackson

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EXHIBIT K

From: Timothy Jackson [<mailto:TEJ@wexlerwallace.com>]
Sent: Sunday, October 29, 2017 7:25 PM
To: David Thomas <DThomas@tcspllc.com>
Cc: Edward Wallace <EAW@wexlerwallace.com>
Subject: Data for Talley et al Article Per Court's September 26, 2017 Order

David,

As discussed on our call Friday, we reached out to Dr. Guelcher immediately after the 9/26/2017 hearing with Judge Eifert and explained to him that the Court had ordered that any "Protocols; Raw data; Information about specimens and materials; and images, such as photographs, taken during the collection of data" be turned over to the defendants. We provided Dr. Guelcher with a copy of the 9/26/2017 Order and went through it with him and he told us that he would reach out to his co-authors, and he has turned over what he received. We provided you with raw FTIR data on 10/20/2017. Dr. Guelcher once again reiterated to us that he had no additional data in his possession which would be responsive to the order.

At Dr. Guelcher's deposition, you asked him if he could get the raw data if he wanted it and Dr. Guelcher explained that he could go to Dr. Dunn to request the data. Dr. Guelcher has explained that he doesn't control his co-authors. This study is one piece of additional literature that supports Dr. Guelcher's existing opinions and it doesn't change his opinions from prior waves, and we believe Dr. Guelcher has taken all reasonable steps to attempt to obtain the data. We can have Dr. Guelcher execute an affidavit to that effect, if you feel that this is necessary.

Tim

Timothy E. Jackson

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EXHIBIT L

From: Timothy Jackson [<mailto:TEJ@wexlerwallace.com>]

Sent: Tuesday, October 31, 2017 4:42 PM

To: David Thomas <DThomas@tcspllc.com>

Cc: Edward Wallace <EAW@wexlerwallace.com>

Subject: Additional Raw Data from Talley et al. Article

David,

Attaching additional raw data from the Talley et al. article that Dr. Guelcher did not previously have access to. We hope that this closes the loop on this issue and that further filings or Court involvement will not be necessary.

Thanks,
Tim

Timothy E. Jackson

WEXLER WALLACE LLP

55 West Monroe, Suite 3300 // Chicago, IL 60603

T 312.346.2222 // F 312.346.0022 // Direct T 312.589.6278

www.wexlerwallace.com

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